

**MELiSSA**



**TECHNICAL NOTE 87.2.14**



**Universitat Autònoma  
de Barcelona**

# ***TECHNICAL NOTE 87.2.14***

**CV detailed engineering datapackage**

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### CHANGE LOG

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## 1. USER MANUAL





## **USER MANUAL**

### **I-BOX TYPE ISOLATORS**

**2 units of 4 glove isolator + transfer chamber  
positioned on a lift table**

**CAREFULLY READ THIS MANUAL BEFORE  
OPERATING YOUR INSTRUMENT.**

Information contained in this document is the property of NOROIT, it may not be duplicated or distributed without NOROIT authorization.

The validity of the instrument's warranty is subject to the observation of the instructions and precautions described in this document.

## REVISION RECORD

INDEX	DATE	AMENDED PAGES	NOTES
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## **TERMS OF WARRANTY**

NOROIT guarantees that the instrument delivered is free from material and workmanship defects when it leaves the factory. If within ONE year of the delivery date, the instrument is proven to be defective under a normal use conditions or during a servicing process, NOROIT undertakes the repair or the replacement of the instrument.

NOROIT's warranty obligations for this product is limited to the repair of the instrument or the replacement of any part of the instrument provided that it is sent, shipping fee paid by client, to an authorised service centre.

This warranty is invalid if the instrument is incorrectly used, improperly serviced or accidentally damaged.

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USER MANUAL  
I-BOX ESA Barcelona

N° doc : 50029

Index : A

## PACKING LIST

ITEM NAME	QUANTITY
User Manual	



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## 1 Uses and Functionalities:

The I-BOX isolators are rigid enclosures for an optimal containment of animals. I-BOX isolators are the best solutions to keep the animals in defined sanitary conditions.



These enclosures are ventilated by a turbulent and sterile-filtered airflow, and free from contaminants by means of the high efficiency input filters.

The isolators can be used in positive pressure for the protection of the animals or in negative pressure for the protection of the environment. The current configuration is: positive pressure.



## 2 Installation Procedure

### 2.1 Lifting and Transport

Due to its weight, all lifting and transporting of the instrument must be done by professionals using proper handling equipment, for example: fork lift trolley, lift tables, and in respects of any applicable handling regulations. Please contact Noroit for any lifting or moving of the equipment.

### 2.2 Environmental Conditions

The instrument should be used under the following conditions:

- i. Indoor
- ii. Temperature: 15°C to 32°C (maximum performance is assured for 15°C to 25°C)
- iii. Maximum relative humidity: 80% for temperatures up to 22°C
- iv. Maximum altitude: 2000m

### 2.3 Main Power Supply

Check to ensure that the instrument has the matching electrical rating as your laboratory before connecting the electrical supply.

The electrical supply for the instrument must have an earthed line. This earthed line must be connected to circuit breaker of appropriate rating, please refer to section 7.5 for rating specifications. The circuit breaker will ensure automatic electricity cut off in the case of short circuit. This constraint is in line with the electrical safety standards for the protection against indirect contact.

Make sure that the instrument's electricity will not be cut off suddenly during usage due to an accidental unplugging of the electrical cord.

### 2.4 Performance Testing

Before its shipment, each I-BOX isolator is tested for:

- its air cleanness. The I-BOX isolator complies with ISO 14644-1 class 100 classification.
- its airflow and pressure.
- its complete tightness.

However, shipping and handling may alter its performance. Therefore, during installation, air cleanness, airflow and pressure, tightness must be re-tested.

**WARNING:** The instrument must be tested by an authorized engineer before use with pathogenic products.

### 3 Specifications

Physical Characteristics	I-BOX ISOLATORS ESA Barcelona
Total height (instrument and support stand)	2m36 (low position)                      3m17 (high position)
Exterior dimensions (H x W x D)	2m36 x 1m10 x 3m
Interior dimensions (H x W x D)	Manipulation chamber : 0.8m x 0.98 x 2m05 Input chamber :                      40.5 cm x 60 cm x 48 cm
Weight (net weight)	630 Kg
Weight (shipping)	750 Kg
Power consumption	550 W max
Voltage	230 V
Frequency	50 Hz



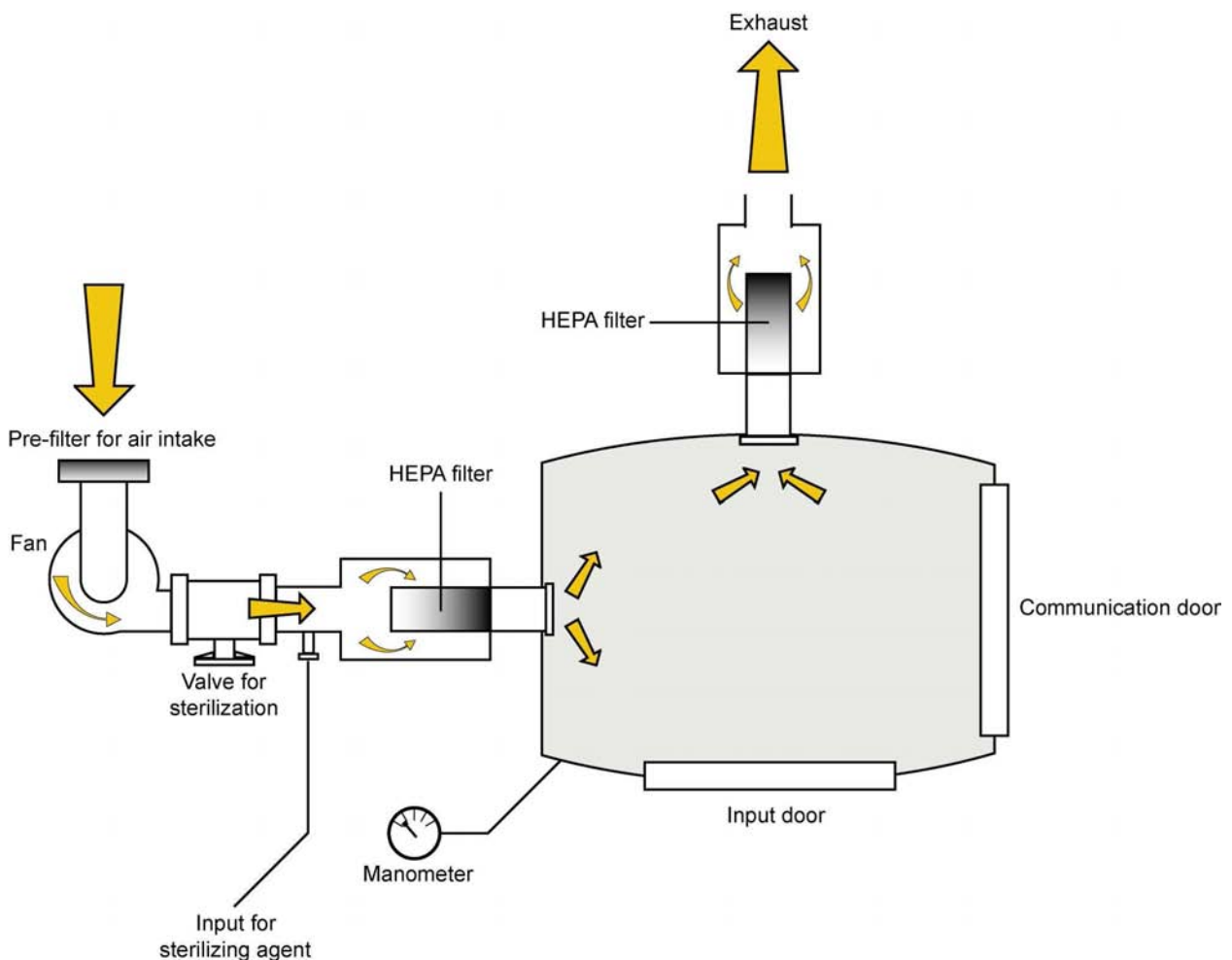
## 4 Operating Principles

### 4.1 Drawings

- **Air flows :**

#### **Input chamber isolator :**

The input chamber is equipped with one fan to position the inside environment in positive pressure. The pressure inside the chamber is measured and monitored.



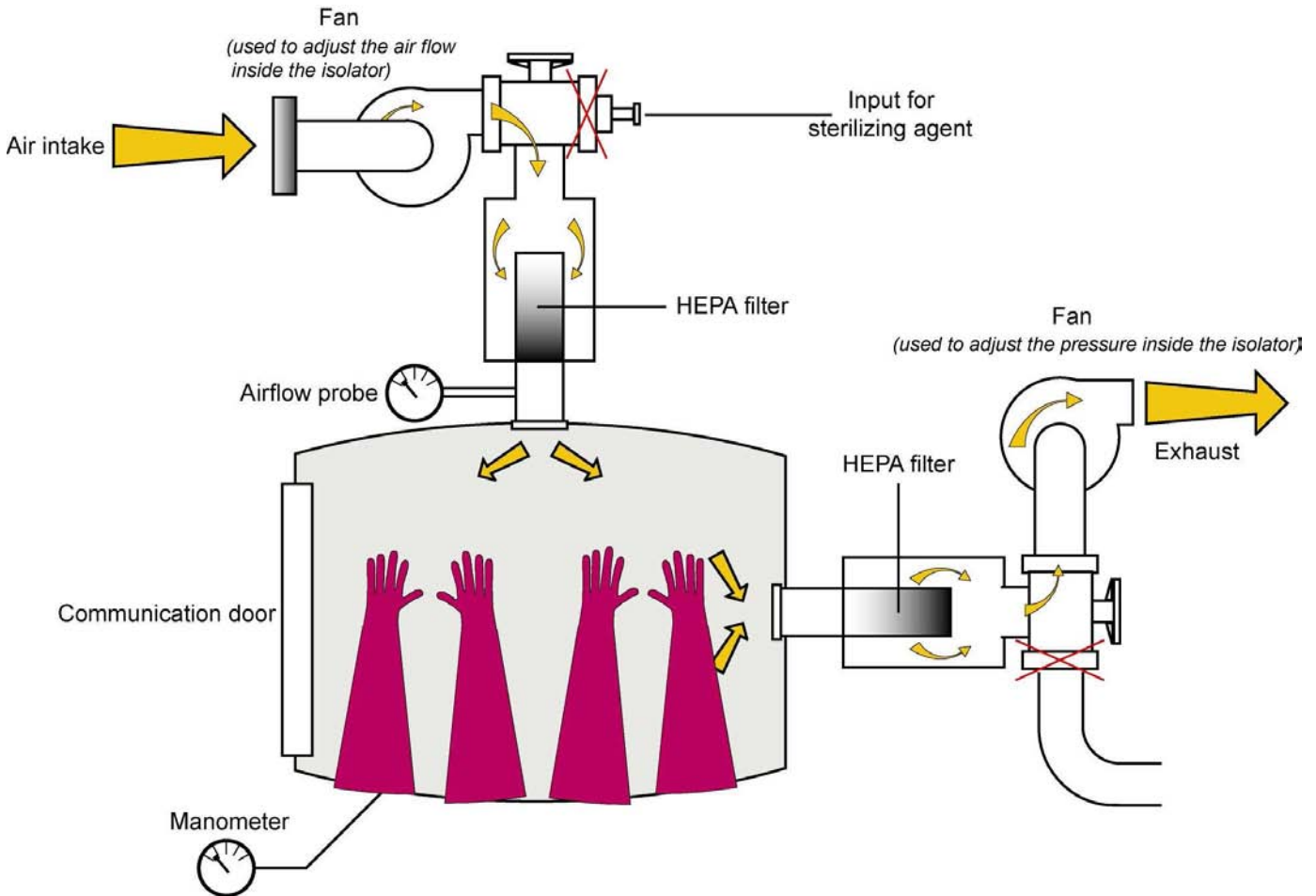
#### **Manipulation isolator :**

The manipulation isolator is equipped with 2 fans. This allows pressure setting as well as air renewal rate setting.

A unique ventilation system does not ensure an absolute safety to the confined animals :  
When the filters progressively clog, the pressure measured inside the isolator raises, and no alarm is triggered, while the airflow delivered to the animals grows poorer days after days.

To avoid this effect, I-BOX controls both the pressure and the air renewal, ensuring the optimal animals welfare.

### Manipulation isolator :



The isolators and transfer chambers are equipped with H13 BAG type filters (99.99% efficiency for 0.3  $\mu\text{m}$  particles). The filters are located at the input and output of the isolators. The manipulation isolators feature double filters at the input and output.

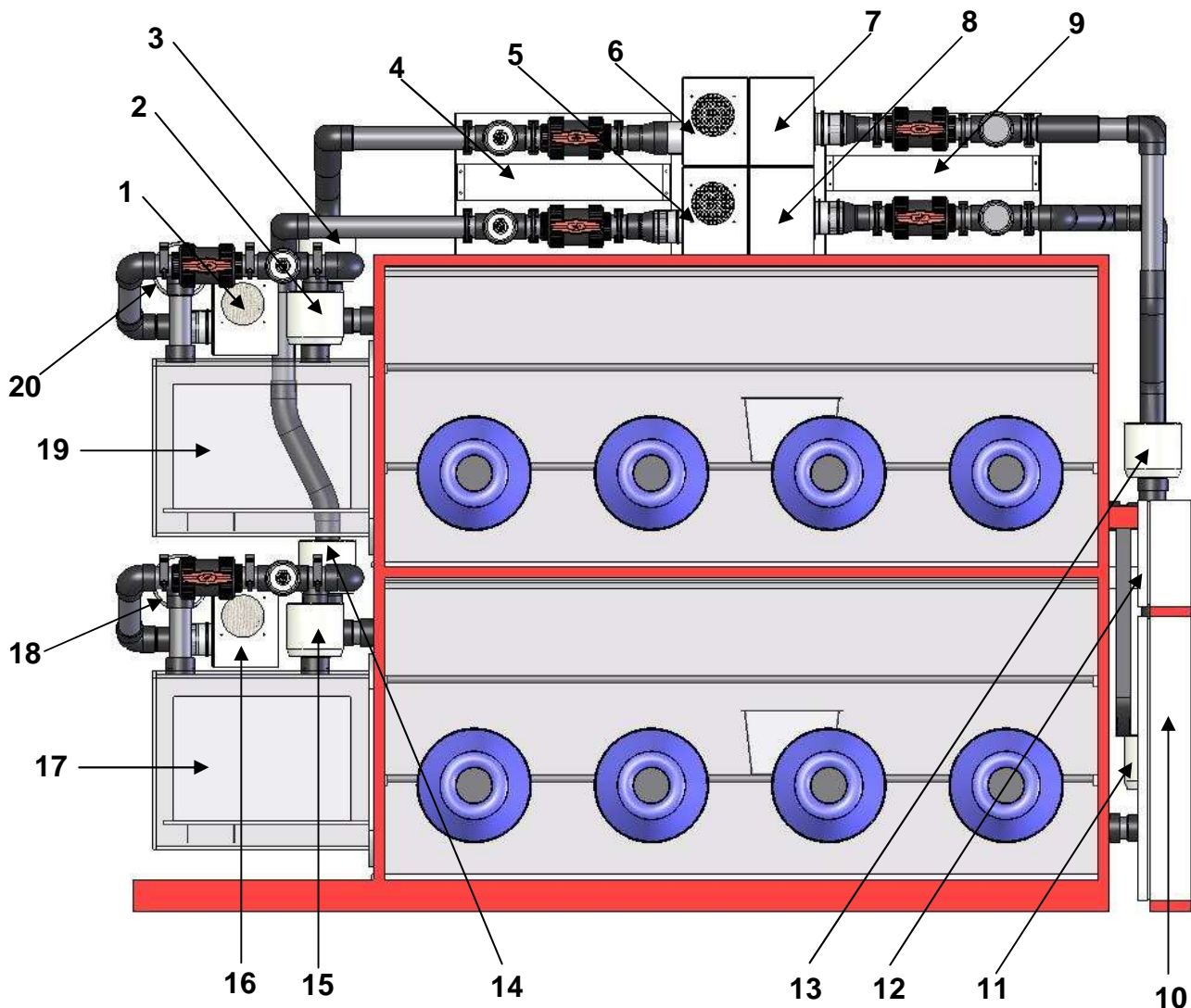
The manipulation chamber is equipped with a temperature and hygrometry probe, located on the connection port

## 4.2 Operating modes :

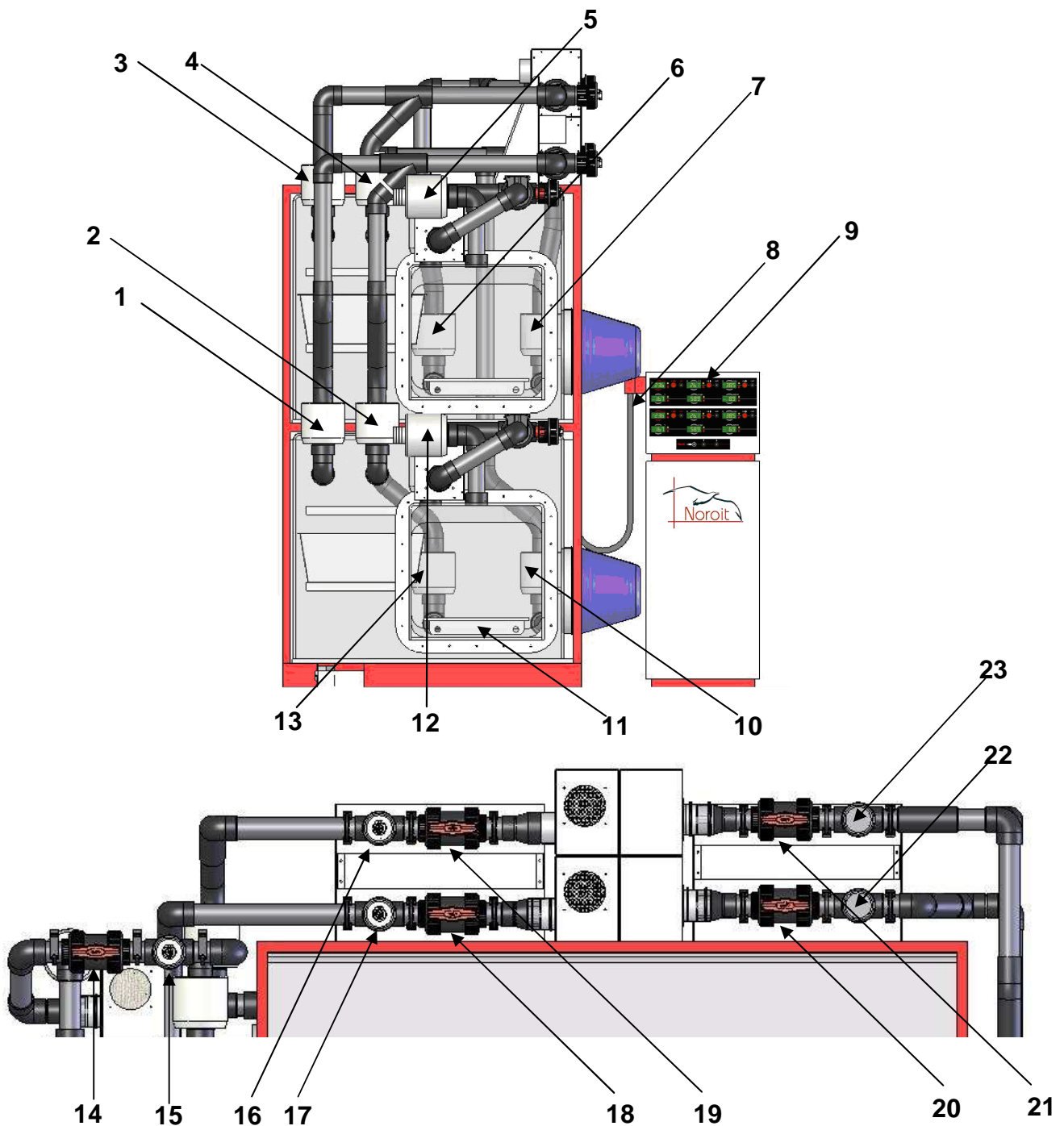
I-BOX has 2 operating modes :

- Normal mode. The fans are running and a positive pressure is set inside the input and manipulation chambers.
- Sterilizing mode. The fans are stopped and disconnected from the ventilation network by means of the  $\varnothing$  63mm valves. Either the input chamber or manipulation chamber is saturated by the sterilizing agent. This mode is described in details, further in this document.

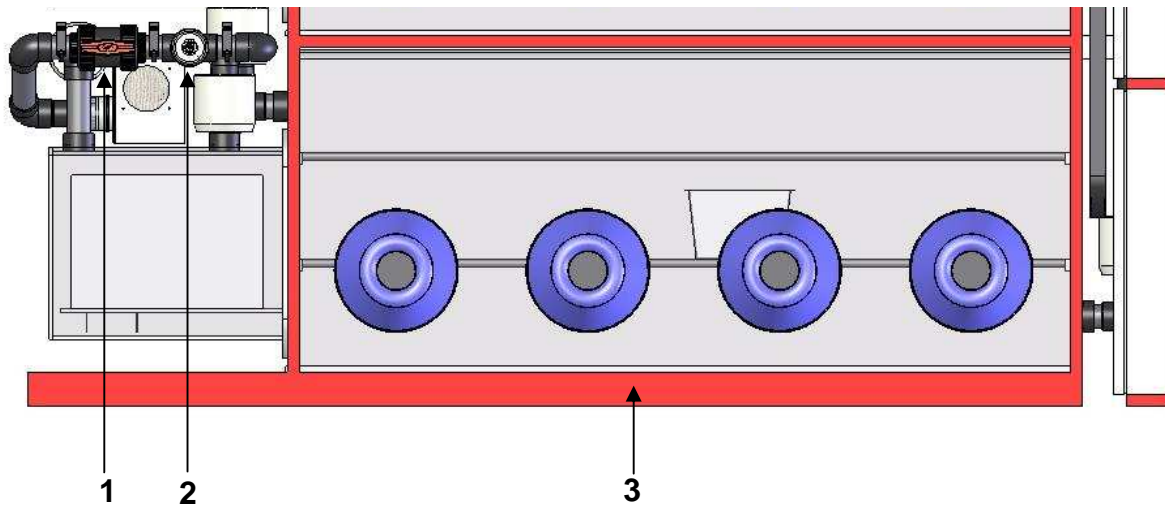
### 4.3 Features :



- 1 Input chamber's fan - Up.
- 2 Input chamber's input filter – Up.
- 3 Manipulation isolator's input filters – Up.
- 4 Electrical compartment – Up isolator.
- 5 Airflow fan, manipulation isolator – Down.
- 6 Airflow fan, manipulation isolator – Up.
- 7 Pressure fan, manipulation isolator – Up.
- 8 Pressure fan, manipulation isolator – Down.
- 9 Electrical compartment – Down isolator.
- 10 Control compartment.
- 11 Manipulation isolator's output filters – Down
- 12 Control panel.
- 13 Manipulation isolator's output filters – Up.
- 14 Manipulation isolator's input filters – Down.
- 15 Input chamber's input filter – Down.
- 16 Input chamber's fan – Down.
- 17 Input chamber – Down.
- 18 Input chamber's output filter – Down.
- 19 Input chamber – Up
- 20 Input chamber's output filter – Up



1	Manipulation isolator's input filter #1 - Low.	12	Input chamber's output filter – Down.
2	Manipulation isolator's input filter #2 – Low.	13	Manipulation isolator's output filter #2 – Down
3	Manipulation isolator's input filter #1 - Up.	14	Input chamber's sterilization valve - Up
4	Manipulation isolator's input filter #2 – Up.	15	Input chamber's connection for sterilizing agent.
5	Input chamber's output filter – Up.	16	Isolator's connection for sterilizing agent – Up.
6	Manipulation isolator's output filter #1 – Up.	17	Isolator's connection for sterilizing agent – Down.
7	Manipulation isolator's output filter #2 – Up.	18	Isolator's sterilization valve #1 - Down.
8	Cables chain.	19	Isolator's sterilization valve #1 - Up.
9	Control panel.	20	Isolator's sterilization valve #2 - Down.
10	Manipulation isolator's output filter #1 – Down.	21	Isolator's sterilization valve #2 - Up
11	Sliding shelf	22	Sterilizing agent exhaust : Low isolator
		23	Sterilizing agent exhaust : Up isolator



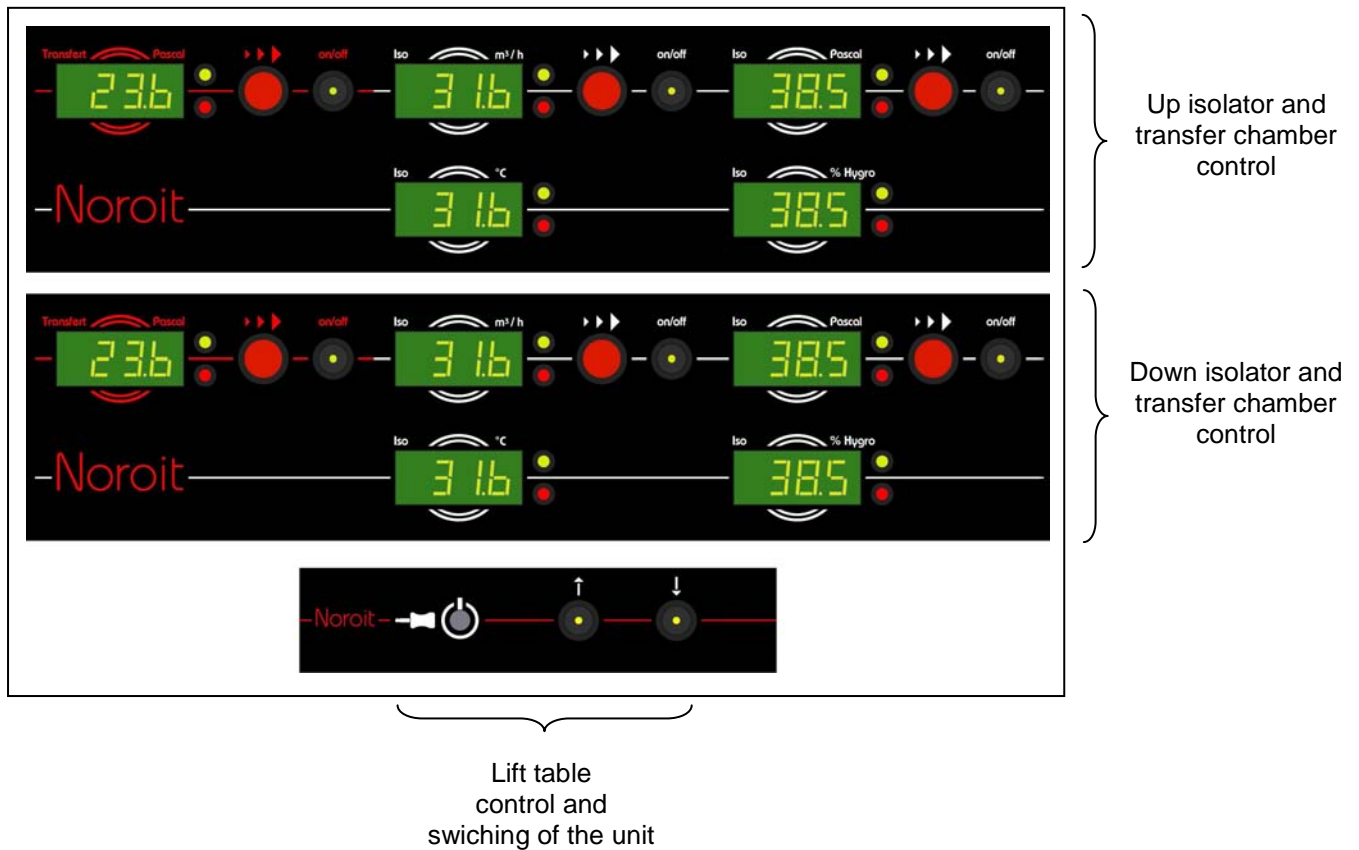
- 1 Input chamber's sterilization valve - Down.
- 2 Input chamber's connection for sterilizing agent - Down.
- 3 Lift table.

## 5 Instructions for Use

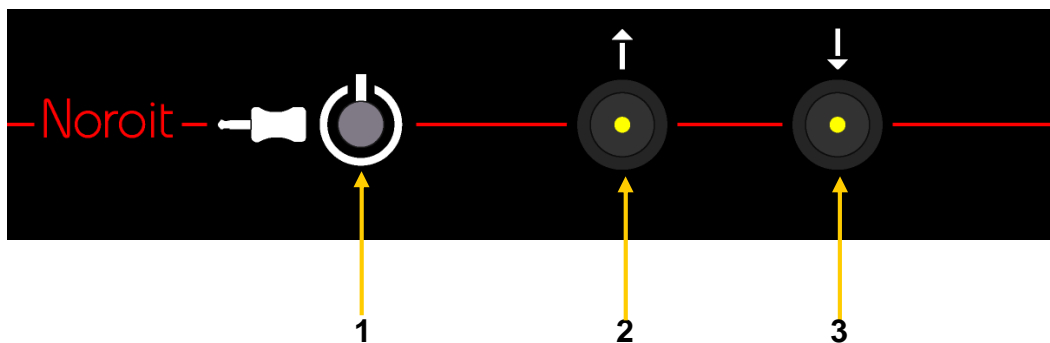
**WARNING:** I-BOX isolators should be used **ONLY** by qualified and trained persons.

### 5.1 General Descriptions :

#### 5.1.1 Control Panels



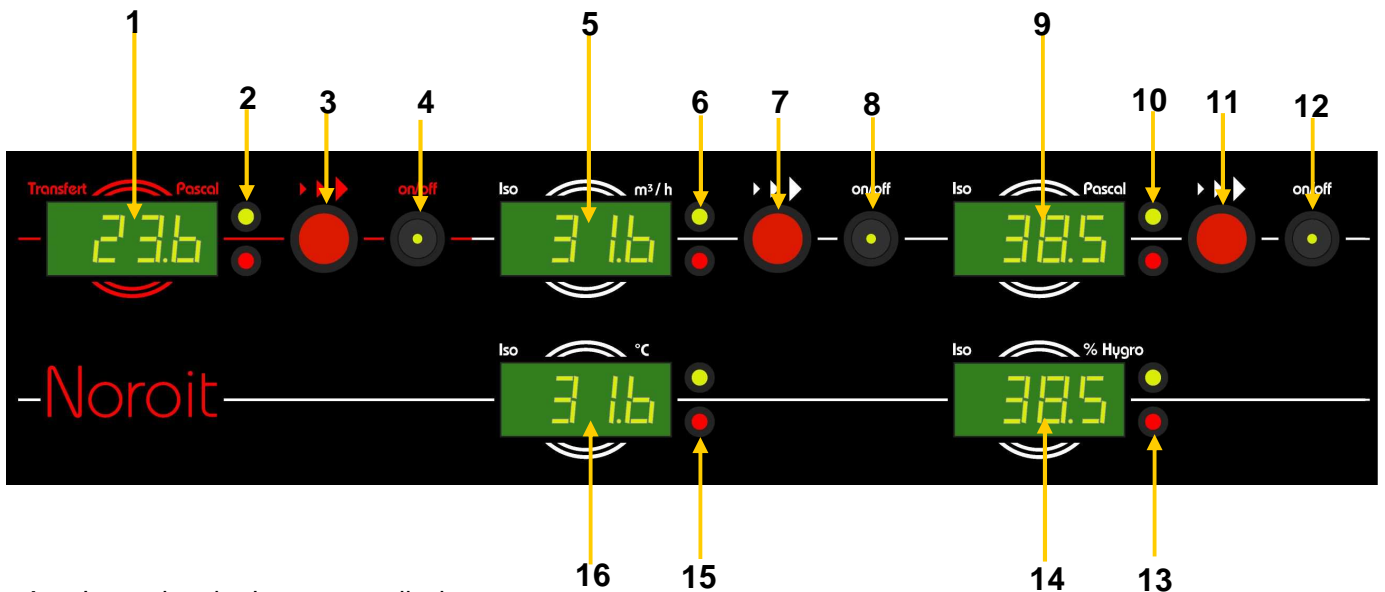
**Table lift and ON/OFF control panel :**



- 1 Electronic key input. Switch on and off the unit.
- 2 Up table. (this button is doubled onto the lift table's control panel)
- 3 Down table (this button is doubled onto the lift table's control panel).

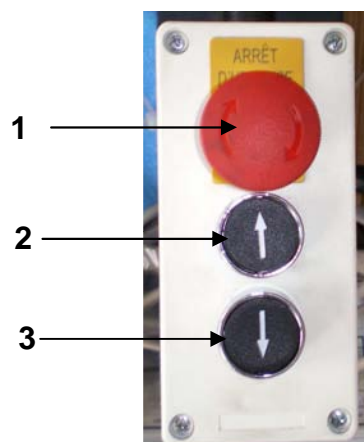


**Up and down isolator control panel :**



- 1 Input chamber's pressure display.
- 2 Input chamber's pressure status leds.
- 3 Input chamber's pressure setting knob.
- 4 Input chamber's pressure "on/off" switch.
- 5 Manipulation isolator's airflow display.
- 6 Manipulation isolator's airflow status leds.
- 7 Manipulation isolator's airflow setting knob.
- 8 Manipulation isolator's airflow "on/off" switch.
- 9 Manipulation isolator's pressure display.
- 10 Manipulation isolator's pressure status leds.
- 11 Manipulation isolator's pressure setting knob.
- 12 Manipulation isolator's pressure "on/off" switch.
- 13 Manipulation isolator's hygrometry status leds.
- 14 Manipulation isolator's hygrometry display
- 15 Manipulation isolator's temperature status leds.
- 16 Manipulation isolator's temperature display

**Table lift control panel :**



- 1 Emergency stop.
- 2 Up table.
- 3 Down table.

**Pressure – airflow knobs : 3 – 6 – 11 :**

Turn clockwise to increase the pressure or airflow.

Please turn slowly this knob. Wait a few second after each slight rotation till the pressure or airflow stabilizes. There is strong inertia between the setting and the effect, especially for large size isolators.

**Fan switch : 4 – 8 – 12 :**

This switch turns on and off the pressure or airflow fan.

When its embedded led is lit, the fan is currently running.

Fans must only be stopped in sterilizing mode.

**Status leds : 2 – 6 – 10 – 13 – 15 :**

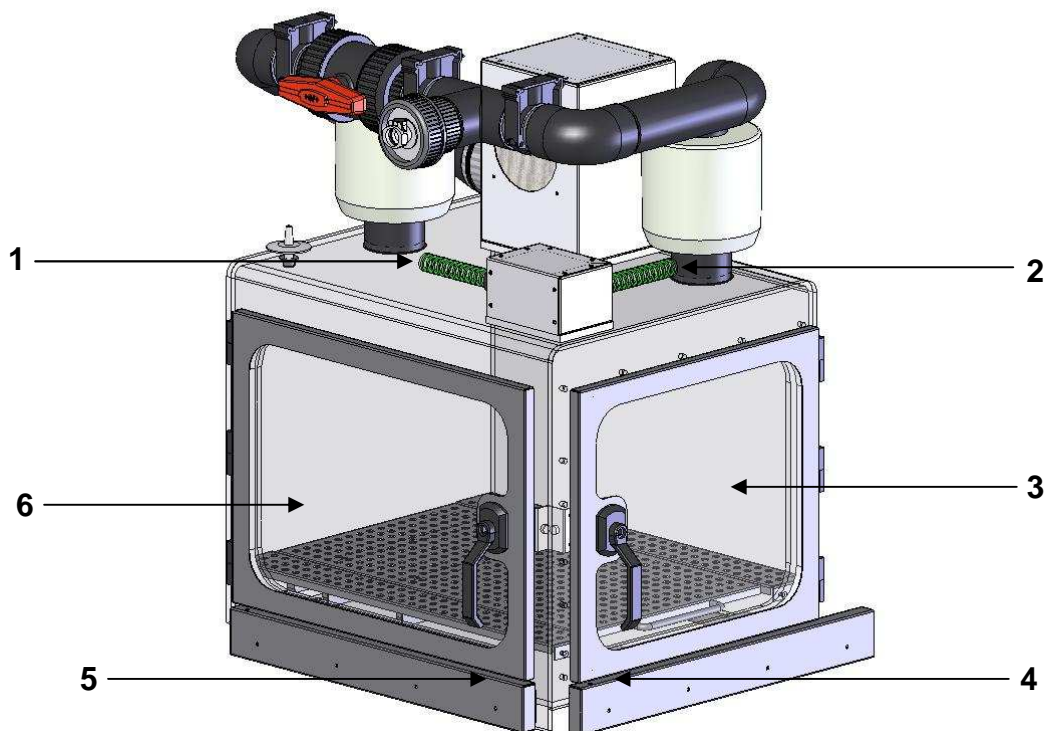
The green led is switched on as long as the measured value remains within the defined alarm threshold.

The red led is switched on when it goes out from this range and after the preset alarm delay.

**5.1.2 Colorsafe system**

Green and red visual warnings are displayed above the input chambers, to prevent the user from inadvertently opening a transfer door.

**WARNING :** The Colorsafe system does not block the doors. It displays a visual information.

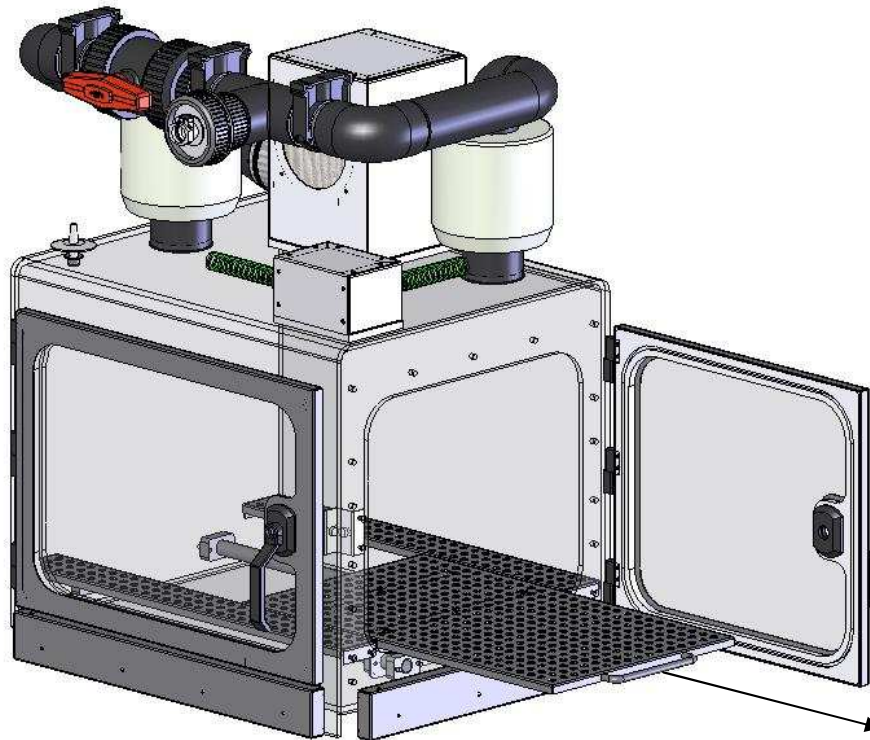


- 1 Input door's opening authorization display :  
Flashes green : Opening the door is granted, the communication door is detected closed.  
Flashes red : Opening of the door is prohibited, the communication door is still opened.
- 2 Communication door's opening authorization display :  
Flashes green : Opening the door is granted, the input door is detected closed.  
Flashes red : Opening of the door is prohibited, the input door is still opened.
- 3 Communication door.
- 4 Communication door's detection sensor.  
Care must be taken to avoid obstructing the detection head.
- 5 Input door's detection sensor.  
Care must be taken to avoid obstructing the detection head.
- 6 Input door.



### 5.1.3 Sliding shelf :

The input chamber is equipped with a sliding shelf to help the transfer of cage toward the manipulation chamber :



Cleaning and preventive maintenance : Use silicon lubricant on the stainless steel tubes.

### 5.1.4 Pre - filters :

Pre - filter are installed inside the chamber to prevent litter or fur to prematurely clog the HEPA filters.

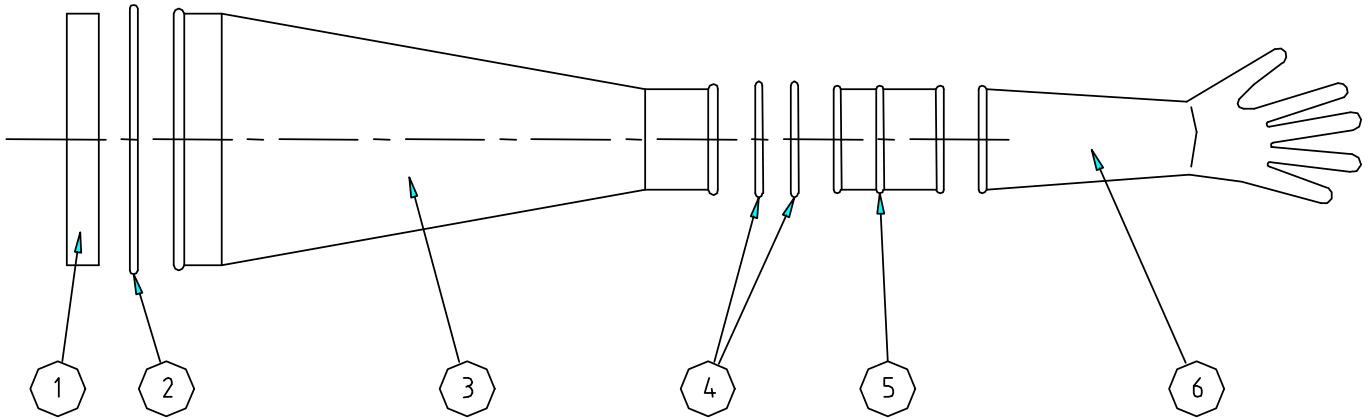
Pre - filter replacement, Ø110mm pre - filter :



### 5.1.5 Gloves and Sleeves :

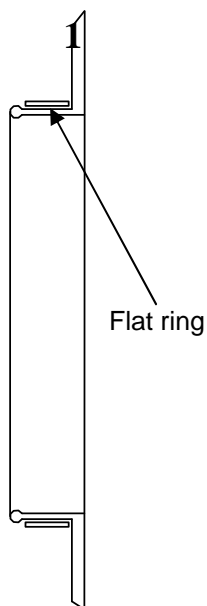
The isolators are equipped with jersey material sleeves with PVC coating, and ambidextrous neoprene gloves.

Contents :

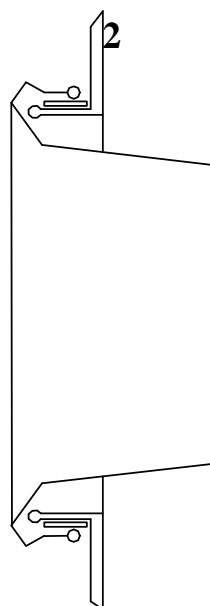


- 1 – Shoulder Flat ring.
- 2 – Shoulder “O” ring.
- 3 – Sleeve
- 4 – Wrist “O” ring
- 5 – Wrist porthole
- 6 – Glove

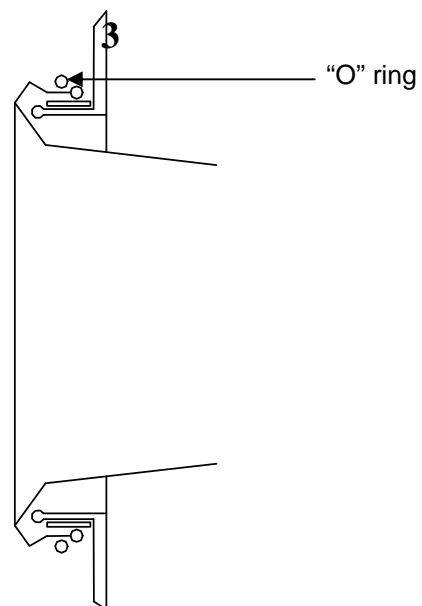
#### Sleeves installation :



Position the flat ring around the shoulder port.

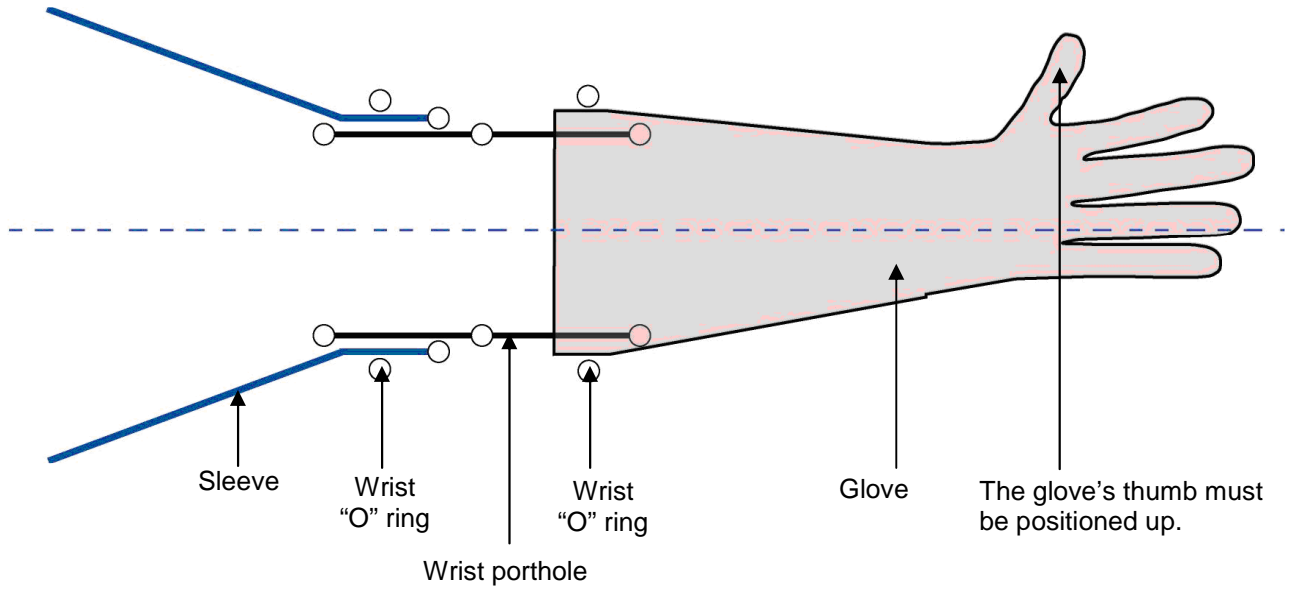


Position the sleeve on top of the flat ring.



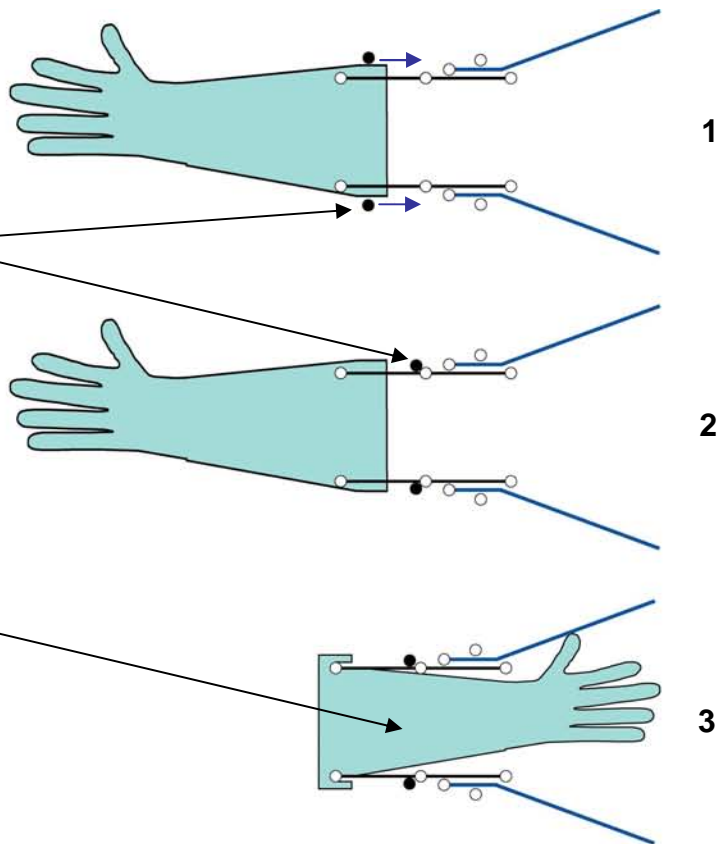
Position the « O » ring on top of the sleeve, around the shoulder port.

**Gloves installation, positive pressure :**

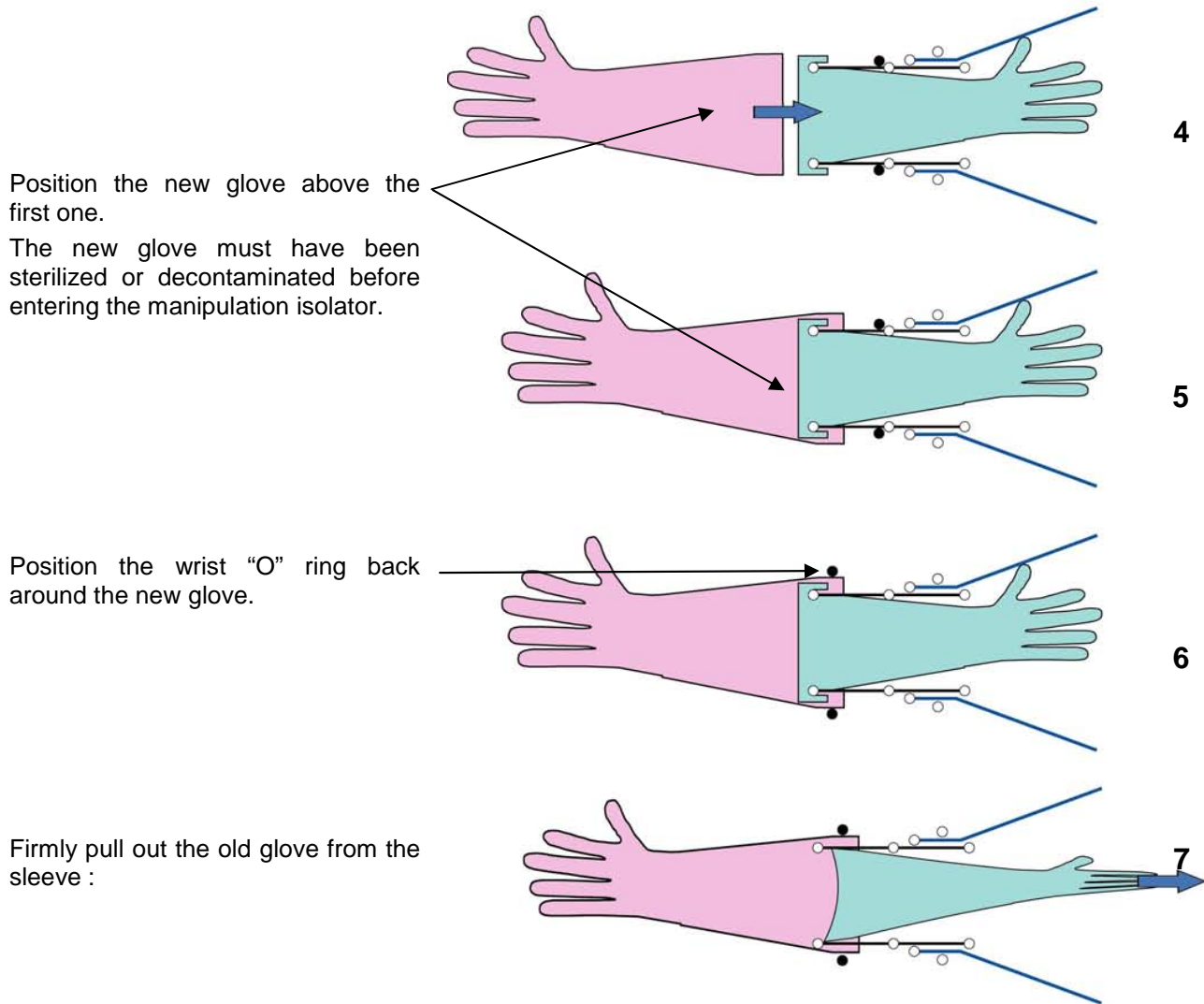


**Gloves replacement, without breaking the confinement :**

Remove the wrist "O" ring from the glove and position it around the wrist port hole.  
As the glove features a built in neoprene ring, confinement is still assured.



Position the glove in reverse side, inside the sleeve. Care must be taken to avoid disconnecting the glove from the wrist porthole.



**Gloves tightness control procedure :**

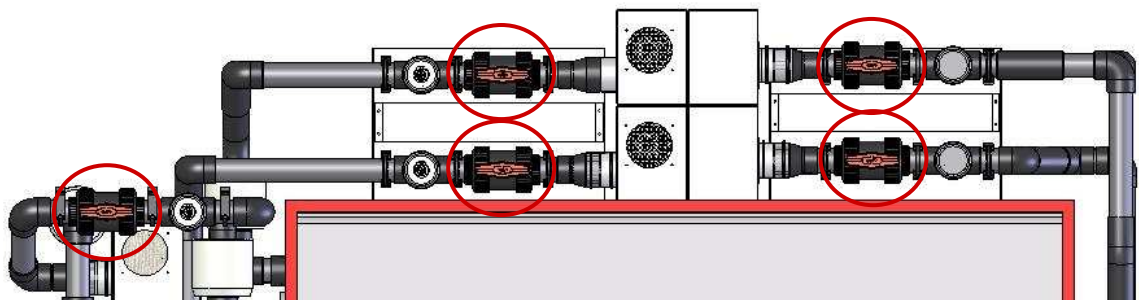
Inflate the glove with air and plunge it in water : if bubbles appear, the glove is unsafe.

**5.2 Using Guide :**

**5.2.1 Switching on the unit :**

**Before switching on the unit:**

- i. Ensure that the valves are positioned in normal mode, ie horizontally :



- ii. Input and communication doors are closed.
- iii. The mains switch, located on the control compartment is positioned "OFF".
- iv. The fan switches are not pressed, ie embedded leds are switched off, fans are stopped ( switches 4 – 8 – 12, up and down isolator)
- v. The knobs are turned anticlockwise, till the stop ( knobs 3 – 6 – 11 )

#### Switch on the unit:

- i. Set the main switch to position "ON".
- ii. Insert the electronic key. Its embedded led flashes green. All displays are switched on, status leds flashes according to their alarm setting. Colorsafe system is also running.
- iii. Press the on/off switch of the input chambers' pressure fan ( 4 ). The switch's embedded led flashes green. Slowly turn the knob ( 3 ) till the pressure displayed is around the defined value, at installation. The status green led is then switched on ( 2 ). The pressure adjustment of the input chamber is now completed.
- iv. The manipulation isolators' pressure must be set before adjusting the airflow.  
Firstly press the on/off switch of the manipulation isolators' pressure fan ( 12 ). The switch's embedded led flashes green. Slowly turn the knob ( 11 ) till the pressure displayed is around the defined value, at installation. The status green led is then switched on ( 10 ).
- v. Secondly press the on/off switch of the manipulation isolators' airflow fan ( 8 ). The switch's embedded led flashes green. Slowly turn the knob ( 7 ) till the airflow displayed is around the defined value, at installation. The status green led is then switched on ( 6 )

**Warning** : Every adjustment must be performed step by step, and slowly. If the airflow's value is too strong, the pressure may be too weak to position the isolator in positive pressure. Hence, the gloves are pumped inside the chamber. Use the pressure's knob (3) to compensate. Whenever the isolator is inadvertently set in negative pressure, the pressure's sensor membrane may remain stuck for a few seconds, and the pressure displayed is 0 Pa. Please wait till it returns to normal state.

#### 5.2.2 Lift table manipulation :

The up and down movement must be soft, free from hiccough.

The velocity remains the same, when it goes down, independently of the load.

If these lift table characteristics change, please consult the maintenance manual, to perform the required adjustment, or contact NOROIT.

The sensitive optical sensors around the table ensure total protection against pinching.

Follow the safety recommendations, as listed above :

- i. Do not exceed the maximum load (900Kg).
- ii. Remove arms from the sleeves prior to any table movement.
- iii. Close the doors prior to any table movement.
- iv. Make sure that every cage is installed correctly on the shelves.
- v. Do not climb on the lift table, especially when it moves.
- vi. Do not obstruct the movement of the table.
- vii. After work completion, always position the table in low position.
- viii. If going under the table is absolutely required :  
Raise the lift table till it reaches its upper position.  
It is then highly recommended to position struts at the 4 corners of the table, and afterwards to lay the table down onto them.  
Switch off the unit (use the emergency stop button).  
Eventually, position a warning panel to clearly indicate : "Lift table servicing in progress".

### 5.2.3 Alarms

To provide users with informative warnings, I-BOX is equipped with different types of alarm.

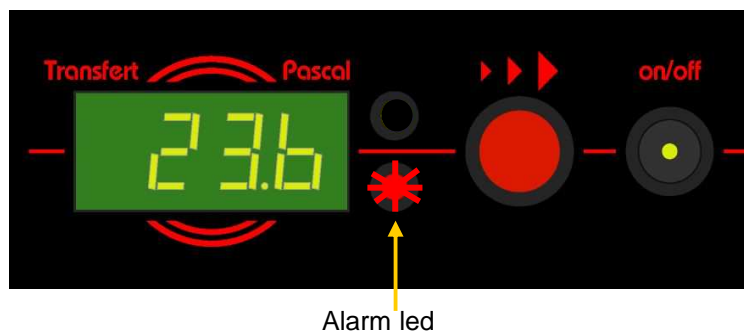
#### 5.2.3.1 Input chamber's pressure alarm :

##### Low alarm :

When the pressure drops below 15 Pa, the visual alarm will be triggered. Visually, the green led will be switched off and the red one will flash. This reduction in pressure may be caused by a clogged filter, defective fan, or bad pressure adjustment.

Actions to be taken:

- Check that there is no item blocking the pre filters.
- Use the knob ( 3 ) to increase the pressure.
- If the knob reaches its maximum stop, the filters must be changed, call NOROIT for servicing the unit.



##### High alarm :

When the pressure increases above 70 Pa, the visual alarm will be triggered, as described above. This increase in pressure may be caused by a defective fan or bad pressure adjustment.

Actions to be taken:

- Use the knob (3) to reduce the pressure.
- If the knob reaches its minimum stop and the alarm is still active, the fan is defective and must be changed, call NOROIT for servicing the unit.

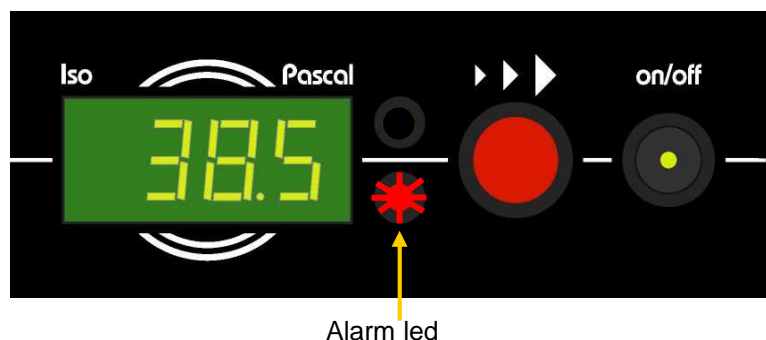
#### 5.2.3.2 Manipulation isolator's pressure alarm :

##### Low alarm :

When the pressure drops below 25 Pa, the visual alarm will be triggered. Visually, the green led will be switched off and the red one will flash. This reduction in pressure may be caused by a clogged filter, defective fan, or bad pressure adjustment.

Actions to be taken:

- Check that there is no item blocking the pre filters.
- Use the knob ( 11 ) to increase the pressure.
- If the knob reaches its maximum stop, the filters must be changed, call NOROIT for servicing the unit.





### High alarm :

When the pressure increases above 75 Pa, the visual alarm will be triggered, as described above. This increase in pressure may be caused by a defective fan or bad pressure adjustment.

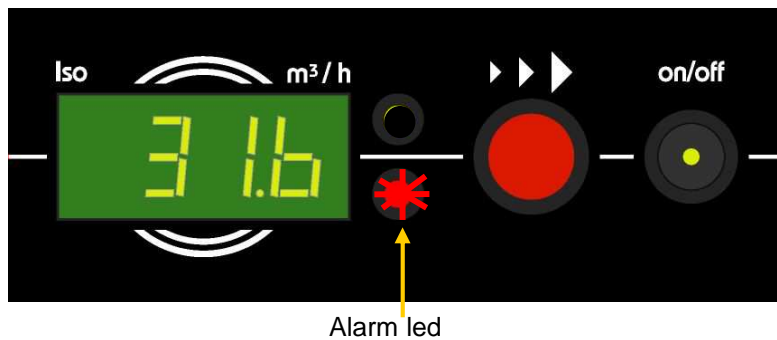
- Actions to be taken:
- Use the knob (3) to reduce the pressure.
  - If the knob reaches its minimum stop and the alarm is still active, the fan is defective and must be changed, call NOROIT for servicing the unit.

### 5.2.3.3 Manipulation isolator's airflow alarm :

#### Low alarm :

When the airflow drops below 30 meter<sup>3</sup> / hour, the visual alarm will be triggered. Visually, the green led will be switched off and the red one will flash. This reduction in airflow may be caused by a clogged filter, defective fan, or bad airflow adjustment.

- Actions to be taken:
- Check that there is no item blocking the pre filters.
  - Use the knob ( 7 ) to increase the airflow.
  - If the knob reaches its maximum stop, the filters must be changed, call NOROIT for servicing the unit.



#### High alarm :

When the airflow increases above 70 meter<sup>3</sup> / hour, the visual alarm will be triggered, as described above. This increase in airflow may be caused by a defective fan or bad pressure adjustment.

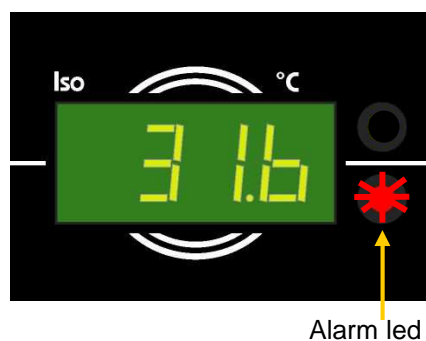
- Actions to be taken:
- Use the knob (7) to reduce the airflow.
  - If the knob reaches its minimum stop and the alarm is still active, the fan is defective and must be changed, call NOROIT for servicing the unit.

### 5.2.3.4 Manipulation isolator's temperature alarm :

#### Low alarm :

When the temperature drops below 15°C, the visual alarm will be triggered. Visually, the green led will be switched off and the red one will flash.

- Actions to be taken:
- Switch on the heating system inside the laboratory.
  - Alternately, you may also slightly reduce the airflow.



### High alarm :

When the temperature increases above 35°C, the visual alarm will be triggered, as described above.

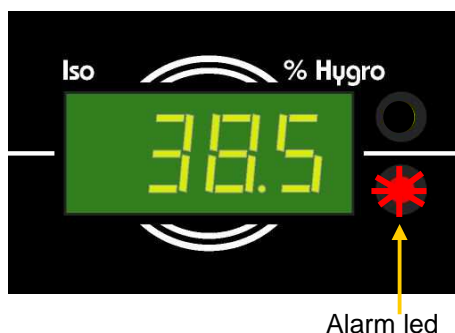
Actions to be taken: - Switch on the air conditioning inside the laboratory.

- Alternately, you may also increase the airflow.

### 5.2.3.5 Manipulation isolator's hygrometry alarm :

#### Low alarm :

When the hygrometry rate drops below 20%, the visual alarm will be triggered. Visually, the green led will be switched off and the red one will flash.



#### High alarm :

When the hygrometry rate increases above 90%, the visual alarm will be triggered, as described above.

Actions to be taken: - Increase the airflow.

### 5.2.4 Work completion

At the end of the manipulation :

- Remove all unused items from the manipulation chamber.
- Make sure that both input and communication doors are closed. Check the "Colorsafe" displays. They must flash green.
- Set the lift table in "Low position".



## 5.3 Sterilization mode :

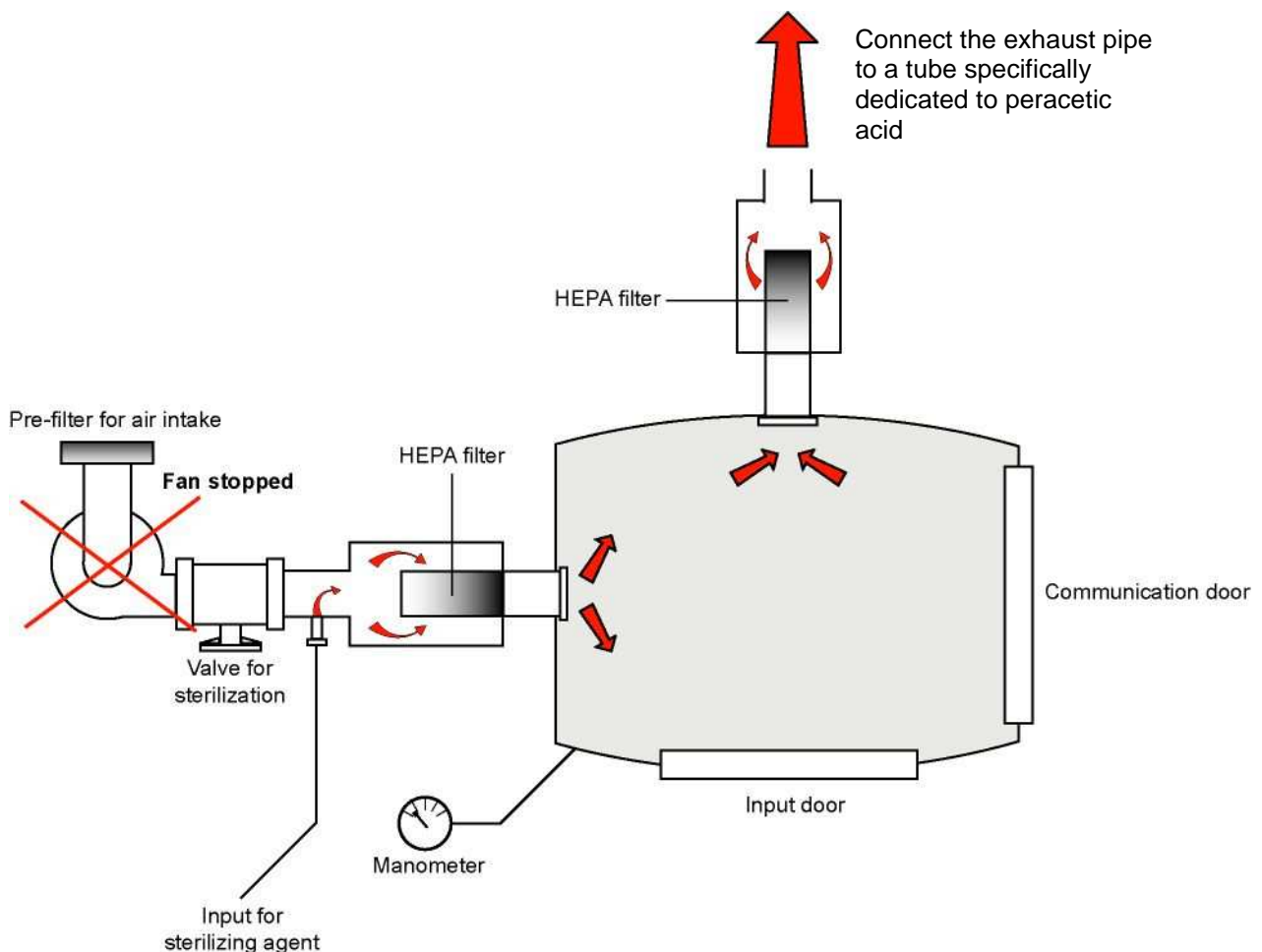
### 5.3.1 Principle :

The internal surface of the isolator is sterilized by means of peracetic acid. This sterilizing agent is firstly heated, till it reaches the “steam” phase, and then spread inside the isolator together with compressed air. Using this technique, the sterilizing agent passes through the HEPA filters.

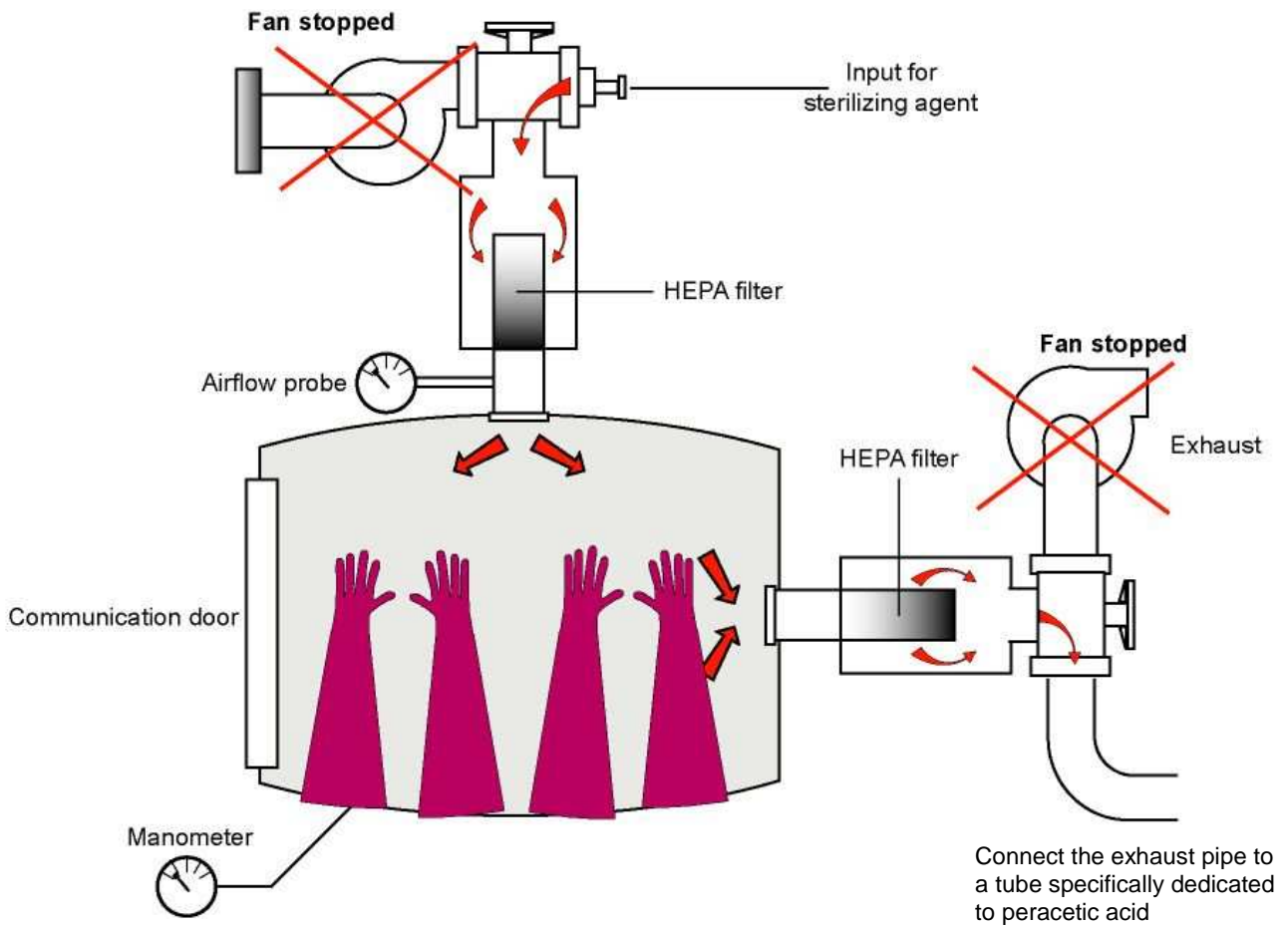
The peracetic acid is very corrosive for steel. Therefore, the fans must be isolated during the sterilizing cycle. Ø63 mm valves are used to achieve this.

### Drawings :

#### Input chamber :



**Manipulation isolator :**



**5.3.2 Procedure before starting a sterilization :**

**5.3.2.1 Fans :**

The pressure fan or both pressure and airflow fans must be stopped before starting a sterilization. Press the dedicated button ( 4 – 8 – 12 ) to stop the fan(s).

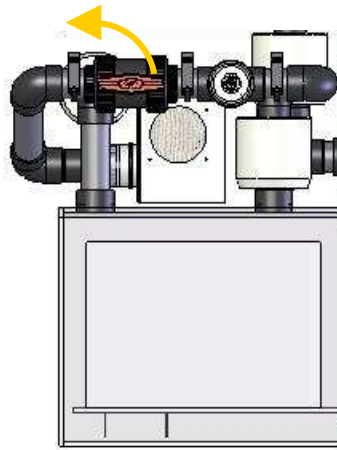
**5.3.2.2 Exhaust connection :**

Connect the output of the ventilation network to the tube dedicated to sterilization, connected to the outside. This tube should be in PVC or stainless steel and its output should be inaccessible to the staff.

**5.3.2.3 Positioning the valves :**

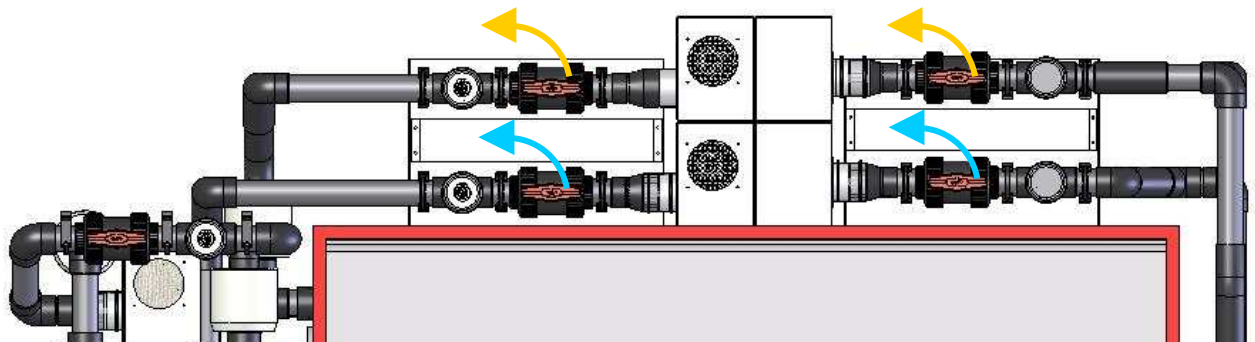
**Input chamber :**



Position the valve vertically, as described hereafter.



**Manipulation isolator :**

Position the valves vertically, as described hereafter.

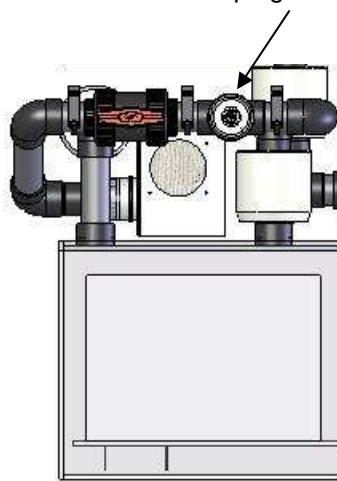


-  Manipulation isolator - Up.
-  Manipulation isolator – Down.

**5.3.2.4 Connecting the sterilizer :**

**Input chamber :**

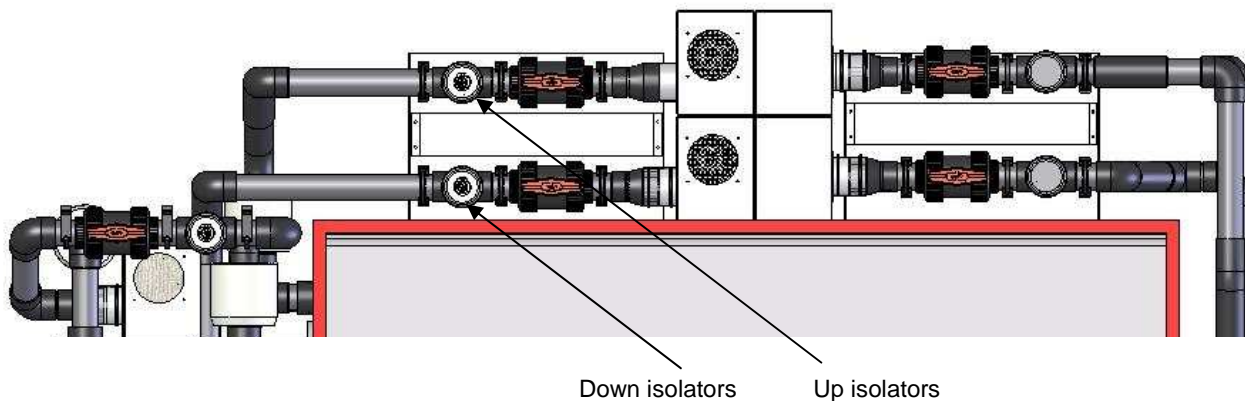
Insert the nozzle of the sterilizer's tube into the fast plug connection.





**Manipulation isolator :**

Insert the nozzle of the sterilizer's tube into the fast plug connection :



Connect the compressed air tube to the sterilizer, if it is not permanently connected.

**5.3.2.5 Warnings :**

The manipulation of hazardous chemical products must only be performed by duly trained staff.

It is compulsory to previously read :

- i. The sterilizer's user manual.
- ii. The warnings and user safety recommendations of the sterilizing agent supplier.

Check that every transfer door is closed.

Check that the load (items to be kept inside the chamber) fulfils the maximum load defined for the sterilizing cycle.

**5.3.3 Launching the sterilization :**

- i. Pour the defined quantity of sterilizing agent inside the sterilizer. (please consult the sterilizer's user manual)
- ii. Launch the sterilizer (please refer to the sterilizer's user manual).

**5.3.4 After sterilization :**

- i. Switch off the sterilizer.
- ii. Position back the valves into the ventilation mode (horizontally).
- iii. Switch on the isolators and transfer chambers fans.

- iv. It is strongly recommended to run the fans for at least 10 minutes before starting any manipulation (flush time).
- v. Disconnect the sterilizer.
- vi. Rinse the sterilizer (Please refer to the sterilizer's user manual)



**For any additional information regarding  
sterilization or use of the sterilizer :**

**PLEASE REFER TO THE STERILIZER'S USER MANUAL.**

## 6 Hazards, Precautions and Limitations of use

### 6.1 General Precautions

When using I-BOX isolators, users must respect the following precautions:

- Always connect I-BOX isolators to an earthed power line.
- Replace filters with recommended HEPA filters only.
- I-BOX isolators must be tested during installation, after each filter change, and after each location change.

### 6.2 Electrical risks

Before carrying out any maintenance services, unplug the I-BOX isolators from the main power outlet. Circuit breaker should be changed only by qualified engineer after the cause of the problem has been determined.

### 6.3 Operational Limitations

#### 6.3.1 Installation

I-BOX isolators must be placed in a well ventilated laboratory, equipped with exhaust pipes, for sterilization. The ground must be flat and regular, to avoid mechanical strength on the lift table jacks.

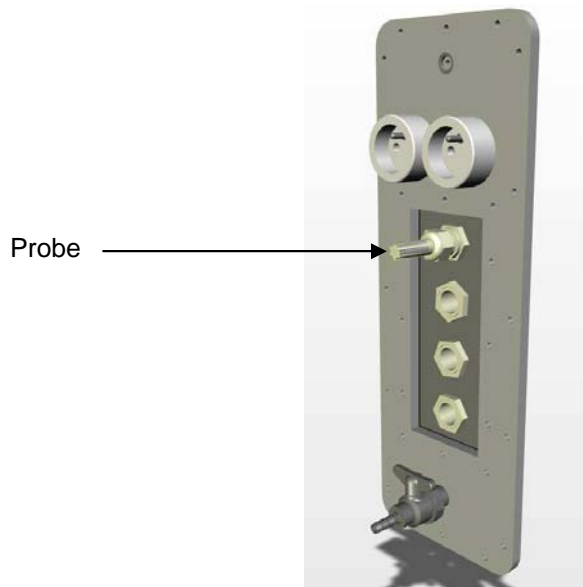
#### 6.3.2 Use of the manipulation chamber

Before beginning with any manipulation work, prepare everything that is needed for the complete procedure. Make sure that the work tray is not overloaded.

Use cautiously materials that disintegrate easily, for example: litter, or cotton. The disintegrated parts can be drawn into the pre-filters and prematurely clog them.

Use cautiously the water tap to avoid spilling water onto the work tray, and especially inside the pre-filters.

Mind the temperature and hygrometry probe located on the connection port. It must not be covered or used to hang any item :



Do not place any items on the pre filters, as they would disturb the airflow and thus reduce the efficacy of the instrument.

## **7 Servicing and Preventive Maintenance**

### **7.1 Cleaning**

If necessary, remove as much dirt or litter as possible from the manipulation isolator before cleaning it with disinfectant. Use a surface disinfectant such as 10% formalin in 70% alcohol or 2% glutaraldehyde.

To clean the work tray :

- Immerse a clean dry cloth in a disinfecting solution.
- Wipe all surfaces.
- Dry them by wiping with clean dry cloth.

To clean the corners of manipulation chamber and the shelves:

- Spray the area with disinfectant.
- Wipe with clean dry mini - broom to dry it.

To clean the canopy :

- Wipe the canopy with mild detergent.



## 2. MAINTENANCE MANUAL



 <p>Noroit Le souffle protecteur</p>	<p>MAINTENANCE MANUAL I-BOX ESA Barcelona</p>	<p>N° doc : 50030 Index : A</p>
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## **MAINTENANCE MANUAL**

### **I-BOX TYPE ISOLATORS**

**2 units of 4 glove isolator + transfer chamber  
positioned on a lift table**

**CAREFULLY READ THIS MANUAL BEFORE  
OPERATING YOUR INSTRUMENT.**

Information contained in this document is the property of NOROIT, it may not be duplicated or distributed without NOROIT authorization.

The validity of the instrument's warranty is subject to the observation of the instructions and precautions described in this document.



MAINTENANCE MANUAL  
I-BOX ESA Barcelona

N° doc : 50030

Index : A

REVISION STATUS

INDEX	DATE	AMMENDED PAGES	NOTES
a	06/09	Creation	



# MAINTENANCE MANUAL I-BOX ESA Barcelona

N° doc : 50030

Index : A

## WARANTEE

Our product is guaranteed for a period of one year against any manufacturing or material defects. This guarantee does not cover consumable items and is subject to the correct application of the installation and operating instructions defined in the manuals supplied with the goods. NOROIT guarantees that we will replace or repair free of charge or credit the purchaser with the full invoice price of any goods or parts of goods of our own manufacture proved to be defective due to faulty workmanship or material defects. This is provided that we are notified in writing of the alleged defect within 12 months of the date of despatch of the goods and that the goods are returned to us promptly on discovery of the alleged defect with details of the manner and circumstances in which they are alleged to have become defective.

Replaced goods become our property.

Goods not manufactured by us are only guaranteed under the guarantee given to us by the actual manufacturers.

Our obligations in respect of defective goods set out above are exclusive and expressly in lieu of all other terms, warranties and conditions expressed or implied (including without prejudice to the generality of the foregoing) warranties and conditions or merchantability and fitness for a particular purpose all of which terms warranties and conditions are hereby expressly excluded.

It is a condition of sale that the purchaser agrees to keep us indemnified at all times in respect of all actions proceedings, claims and demands whatsoever which may be made by any third party against us for any loss or damage howsoever arising (including with prejudice to the generality of the foregoing loss or damage arising out of the negligence of our employees or agents) which may be caused by goods sold to the purchaser, and all costs and expenses incurred by us in connection therewith.

All liability for loss of profit, consequential loss, or any other loss whatsoever suffered by the purchaser howsoever arising (including without prejudice to the generality of the foregoing loss arising out of our negligence of our servants or agents) is hereby expressly excluded.

In the event that a purchaser makes any claims for such loss or damage against any of our employees or agents, it shall pay to us the amount (if any) recovered from such employee or agent and an amount equal to the legal costs (on a full indemnity basis) incurred by such employee or agent in defending or compromising the purchaser's claim).

### FOR MORE INFORMATION, PLEASE CONTACT :

**NOROIT**  
**Rezé Créatic**  
**2, rue Robert Schuman**  
**44400 Rezé**  
**Tel : 332.40.50.12.77**  
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[www.noroitlabo.com](http://www.noroitlabo.com)



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## CHAPTER 1 : OVERVIEW

### 1.1. PURPOSE

This manual contains technical information for use by qualified maintenance engineers, theory of operation, specification, help in diagnosing faults, some adjustment procedures and parts replacement.

Only qualified engineers are permitted to carry out servicing or repairs which are beyond the scope of the operations described in the user manual.

In case of difficulty, please ask the authorized service organization in your area for assistance, or contact our sales department:

#### AFTER SALES SERVICE :

**NOROIT**  
**Rezé Créatic**  
**2, rue Robert Schuman**  
**44400 Rezé**  
**Tel : 332.40.50.12.77**  
**Fax : 332.51.70.20.25**

[contact@noroitlabo.com](mailto:contact@noroitlabo.com)

### 1.2. DESCRIPTION

I-BOX isolators ensure total protection of the user, the manipulation and the environment, by means of :

- Absolute tightness of the chamber.
- Positive or negative pressure inside the chamber.
- High efficiency filtering (99.99% for 0,3 µm particles)
- Physical barrier (fiberglass body and gloves) between the user and potentially dangerous handled materials.

It also permits operation in a sterile environment.

The performance of this type of equipment depends not only on the instrument itself but also upon the following parameters:

- The user: Use of isolators must be reserved for qualified personnel having received suitable training.
- Servicing: the filters efficiency and the air cleanness measurement must be checked regularly and at preferably, once a year.

### 1.3. SPECIFICATIONS

Specifications	ISOLATORS FOR ESA BARCELONA	
Total height (instrument and support stand)	2m36 (low position)	3m17 (high position)
Exterior dimensions (H x W x D)	2m36 x 1m10 x 3m	
Interior dimensions (H x W x D)	Manipulation chamber : 0.8m x 0.98 x 2m05 Input chamber : 40.5 cm x 60 cm x 48 cm	
Weight (net weight)	630 Kg	
Weight (shipping)	750 Kg	
Power consumption	550 W max	
Voltage	230 V	
Frequency	50 Hz	

## CHAPTER 2

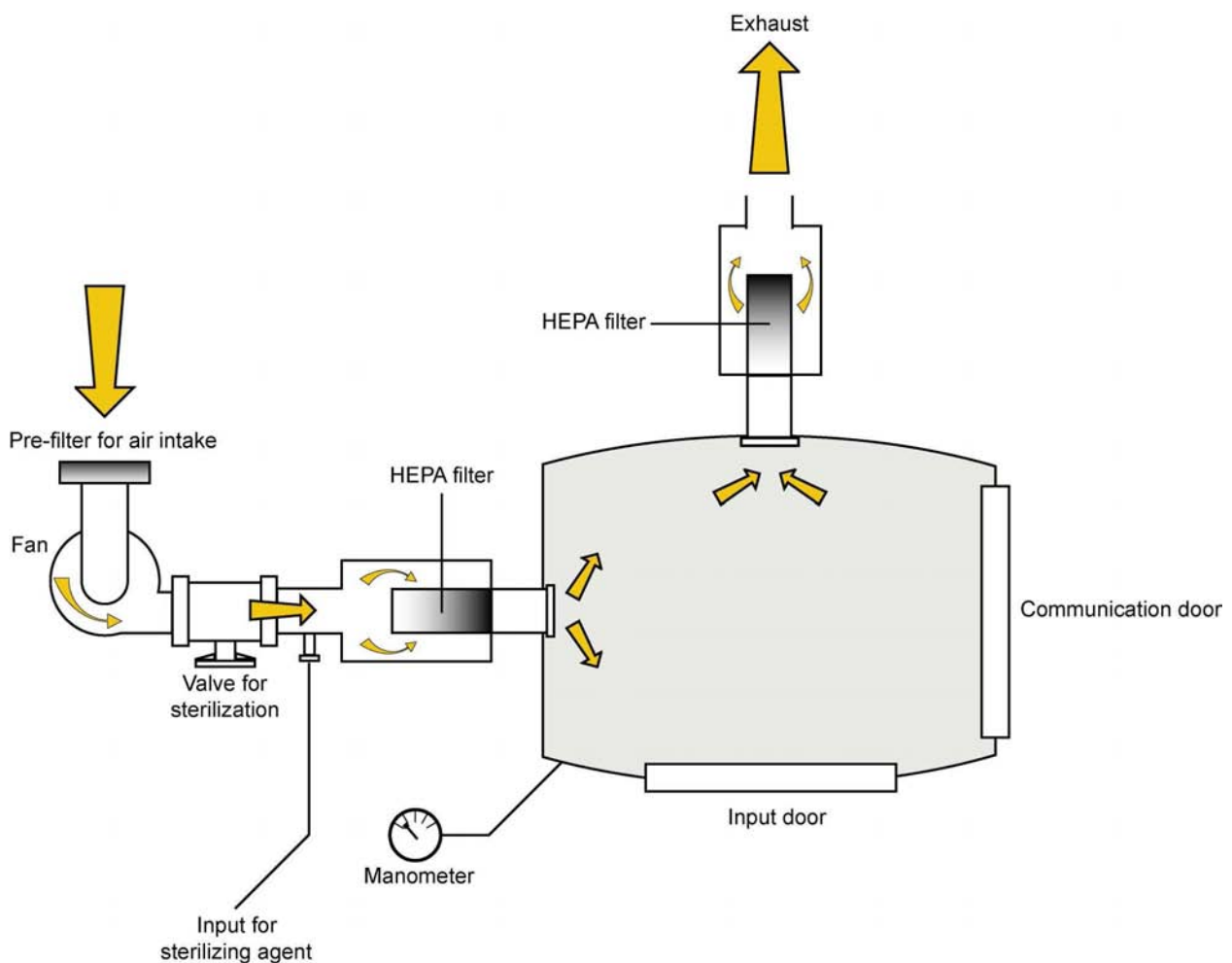
### THEORY OF OPERATION

#### 2.1. FUNCTIONAL DESCRIPTION

The isolators are rigid enclosures for an optimal containment of animals. They are the best solution to keep animals in defined sanitary conditions. The use of isolators in positive pressure is made while the animals protection is required during manipulation. Examples: animals with a Specific Pathogen Free sanitary status, Nude mice, etc...

##### Input chamber isolator :

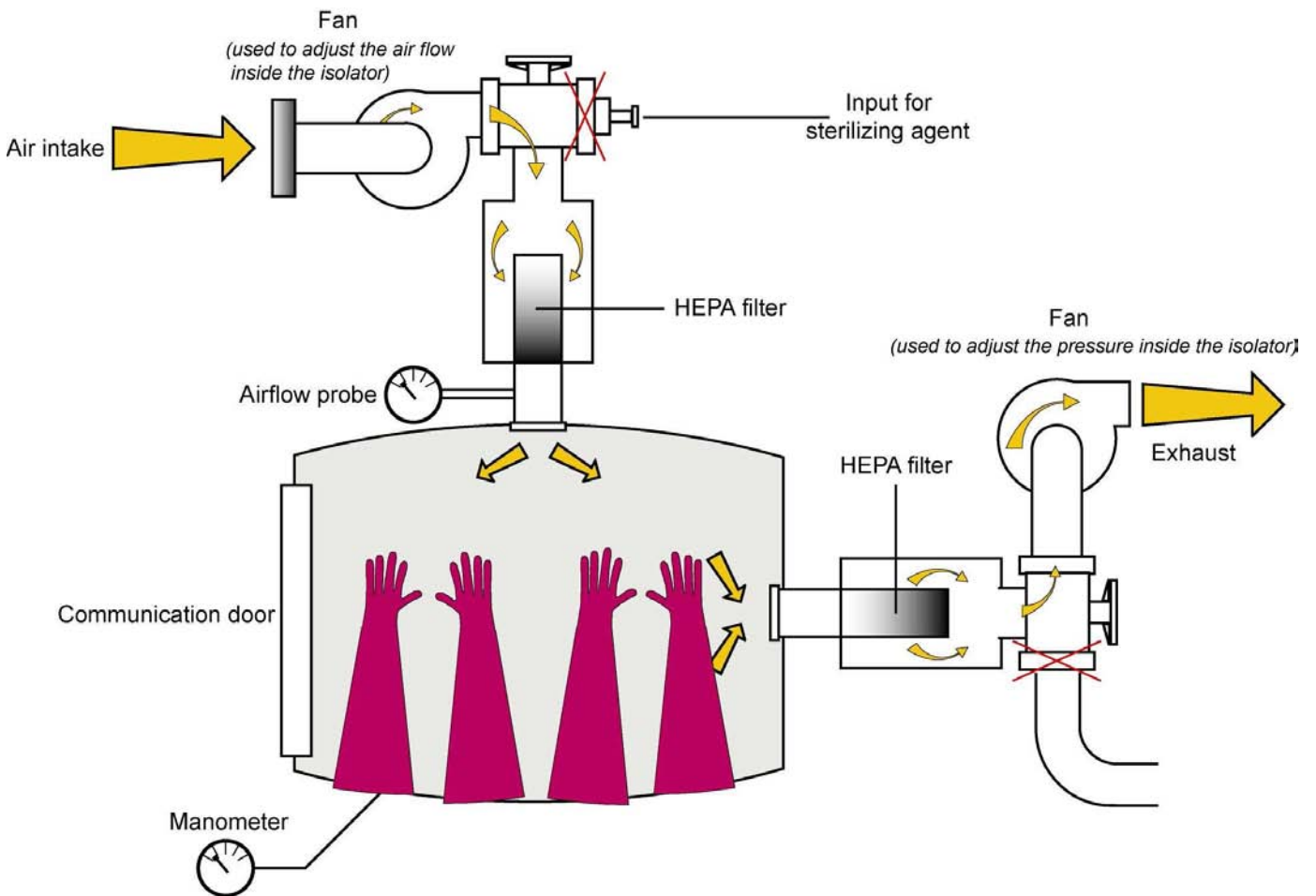
The input chamber is equipped with one fan to position the inside environment in positive pressure. The pressure inside the chamber is measured and monitored.



##### Manipulation isolator :

The manipulation isolator is equipped with 2 fans. This allows pressure setting as well as air renewal rate setting.

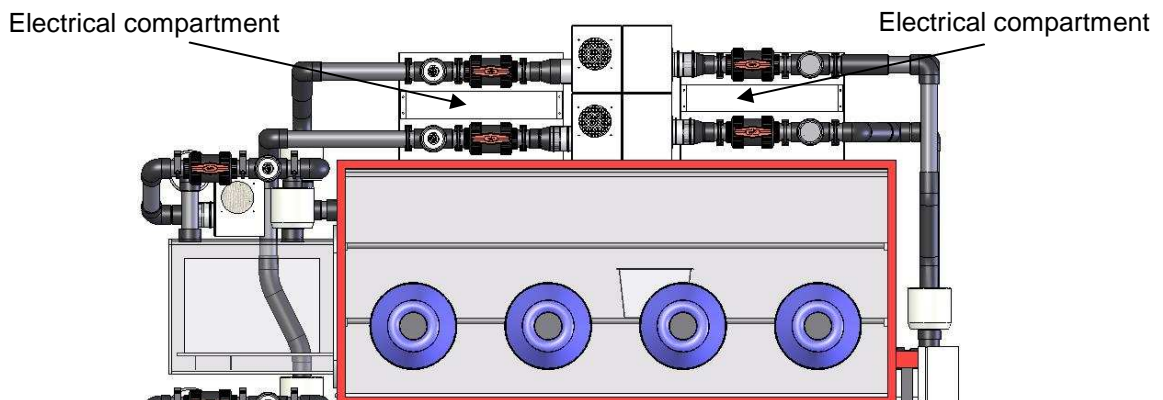
**Manipulation isolator :**



The isolators and transfer chambers are equipped with H13 BAG type filters (99.99% efficiency for 0.3 µm particles). The filters are located at the input and output of the isolators. The manipulation isolators feature double filters at the input and output. The manipulation chamber is equipped with a temperature and hygrometry probe, located on the connection port

**2.2. ELECTRICAL COMPARTMENT DESCRIPTION**

The unit features 2 electrical compartments, located above the top isolator.





The right one controls the low isolator and input chamber.

The left one controls the up isolator and input chamber.

A microprocessor logic system and its embedded software control each isolator and input chamber.

The airflow velocity is measured by an anemometer inserted inside the ventilation network.

The pressure is measured by a membrane type probe connected to a plastic tube inserted inside the chamber.

Temperature and hygrometry inside the manipulation isolator are measured by a probe located onto the connection port.

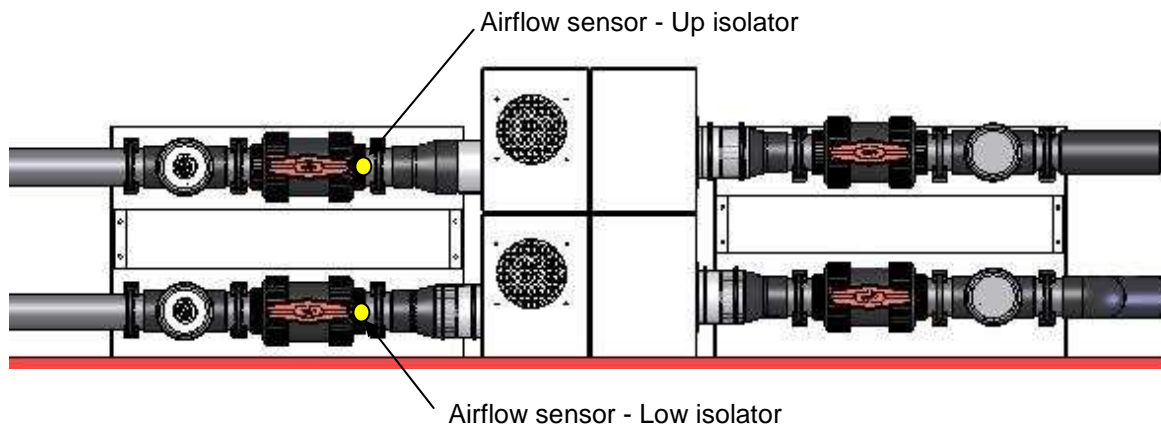
These measures are converted into digital form for analysis by the microprocessor system.

The microprocessor system uses the measurements to determine alarm triggering.

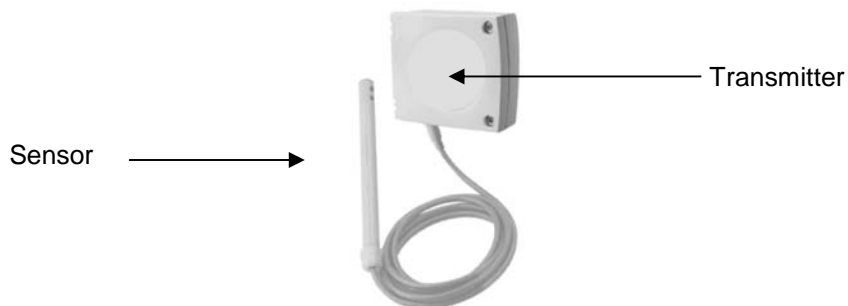
The microprocessor system also takes into account the opening and closing of the transfer doors, to control the colorsafe system.

### 2.2.1 AIRFLOW MEASUREMENT :

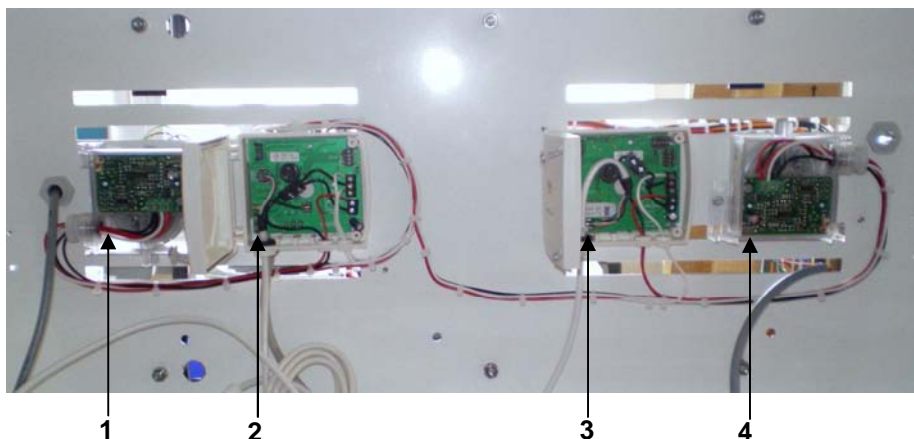
The airflow is measured by a "Kimo" sensor located inside the ventilation network.



This sensor is connected to an electronic transmitter. When it needs to be replaced, the whole equipment must be removed :



The transmitter is mounted on the other side of the electrical compartment :



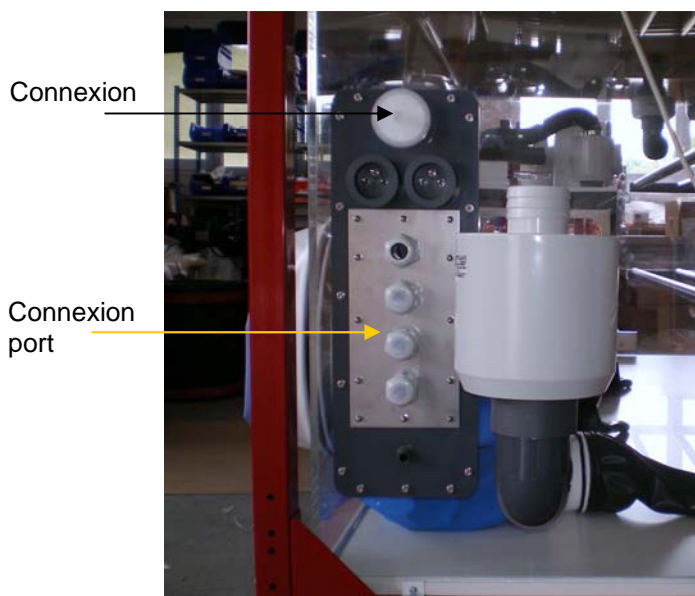
The transmitter boxes are opened to show the embedded electronic board.

- 1 Pressure transmitter – Manipulation isolator.
- 2 Temperature and hygrometry transmitter.
- 3 Airflow transmitter.
- 4 Pressure transmitter – Input chamber.

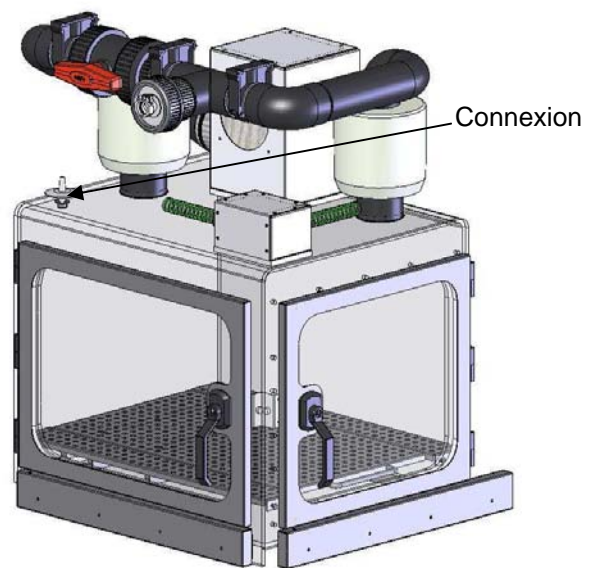
### **2.2.2 PRESSURE MEASUREMENT :**

Each pressure (for manipulation isolator and input chamber) is measured by a “Huba control” transmitter located at the rear of the electrical compartment, as described above.

This transmitter is connected to a plastic tube which outputs inside the manipulation isolator or transfer chamber, through a small Millipore absolute filter :



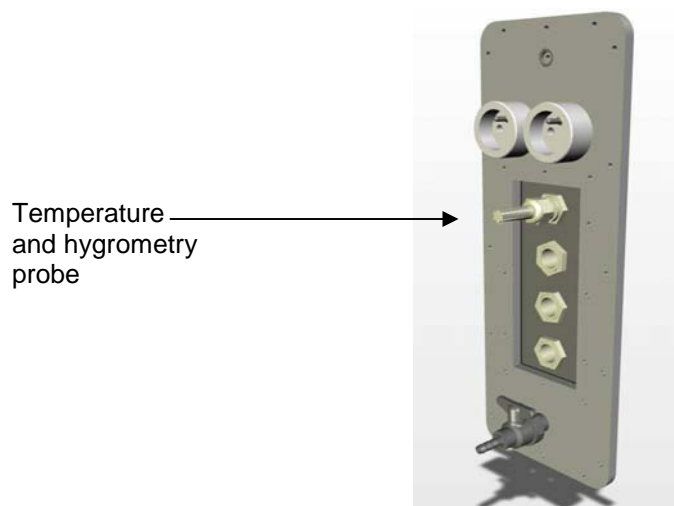
Manipulation isolator : Pressure tube connexion.




Input chamber : Pressure tube connexion

### **2.2.3 TEMPERATURE AND HYGROMETRY MEASUREMENT :**

The temperature and hygrometry are measured by a “Kimo” sensor located inside the connexion port of the manipulation isolator. The transmitter is located at the rear of the electrical compartment as described above.



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### **2.3 ALARMS**

Please refer to the user manual, for a complete description of the alarms.

### CHAPTER 3 :

#### REPLACEMENT PROCEDURES

Replacement of spare parts and adjustments are done using the standard tools of a maintenance engineer specialised in laboratory equipment. As a guide, a list is given in the appendix. If, for a particular reason, any other tools are required, these are clearly specified in the relevant chapter.

#### **3.1 ELECTRICAL COMPARTMENT :**

For the following operations, the electrical compartment must be opened.

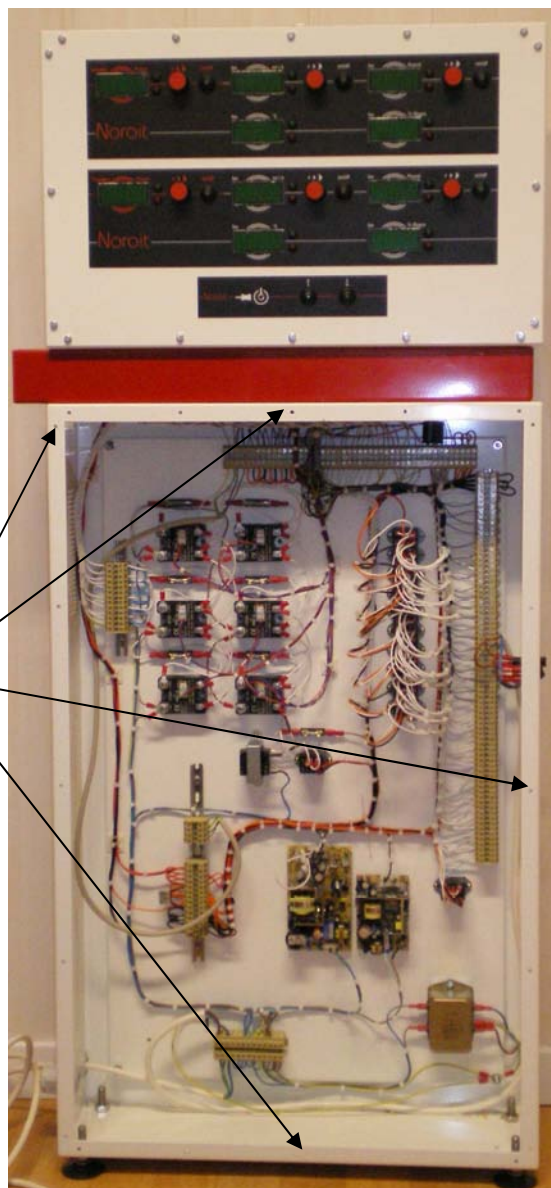
Procedure:

**UNPLUG THE EQUIPMENT FROM MAINS**

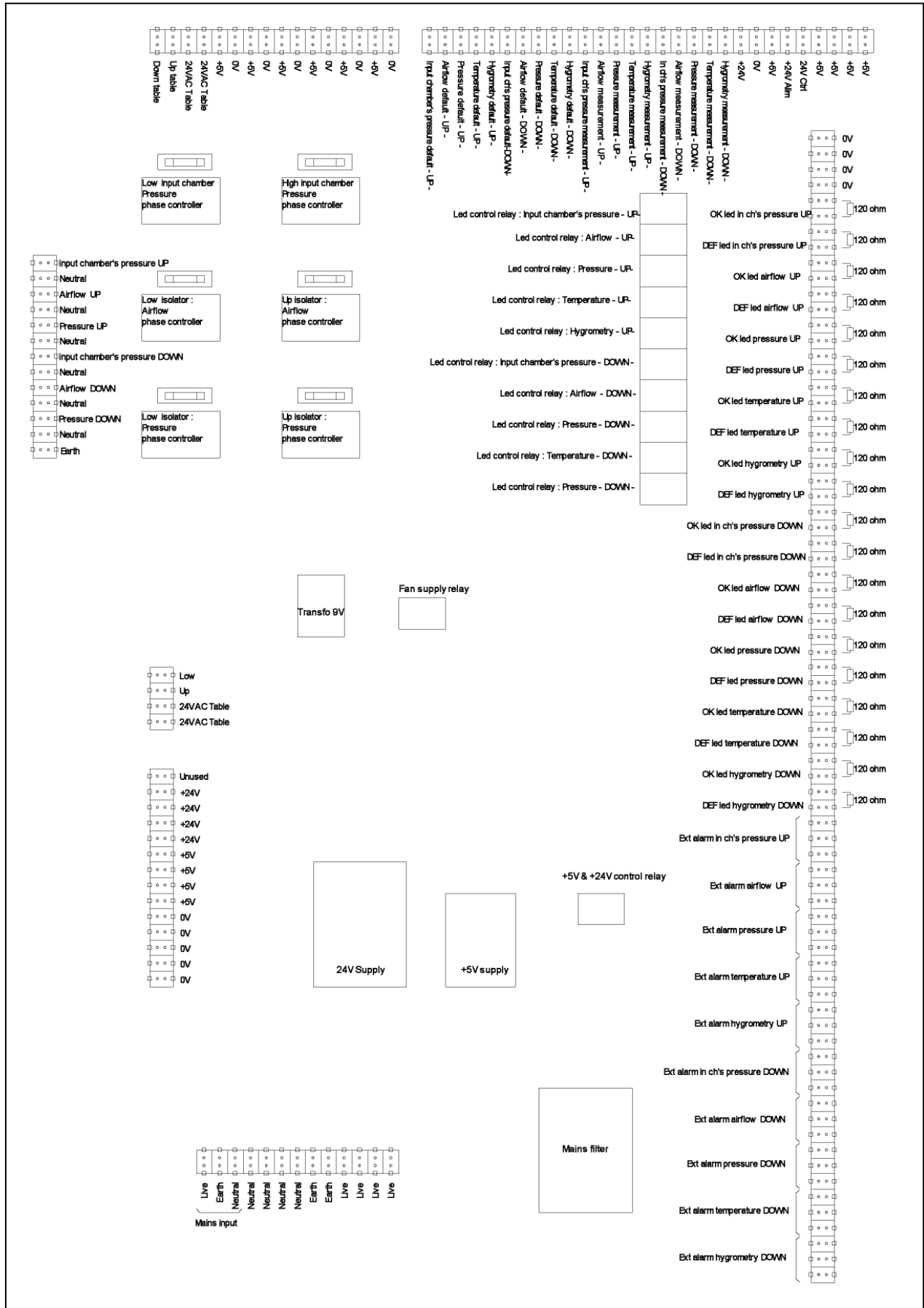
Remove the 20 screws from the front panel.

Unscrew the 20 front  
panel locking screws.

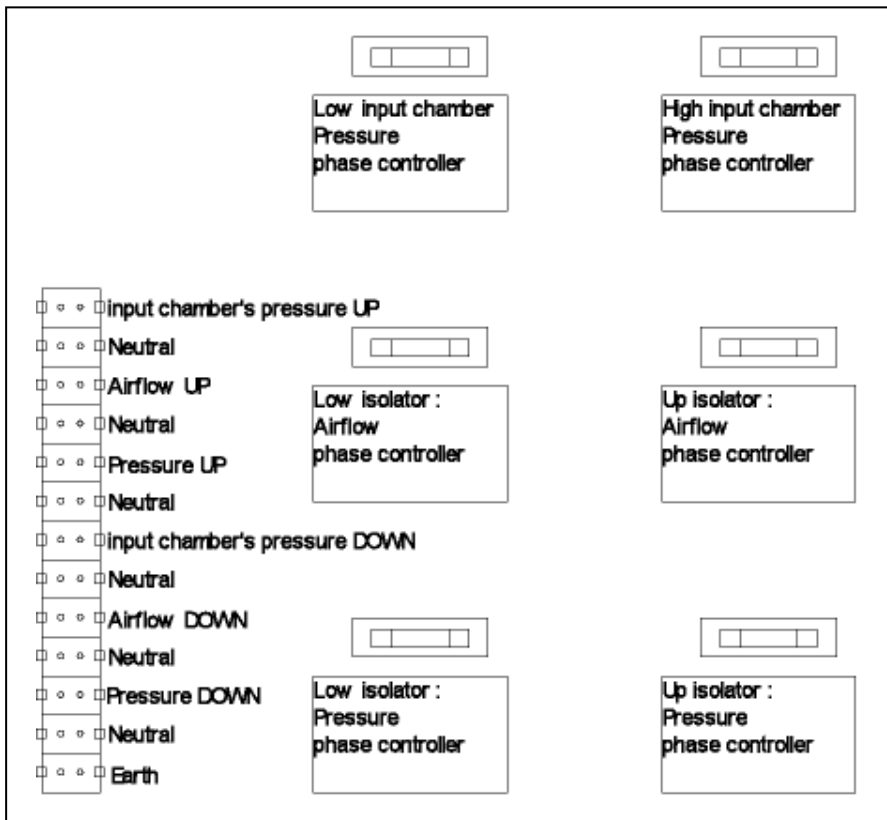
H4 Head screw – 7  
mm wrench



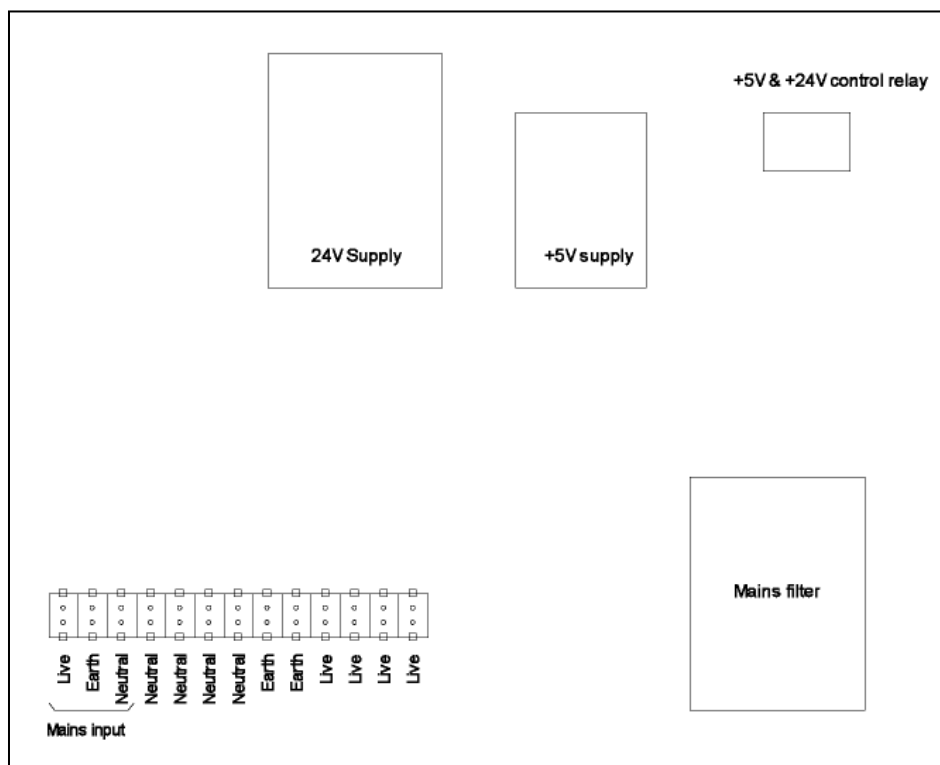
### Overview :



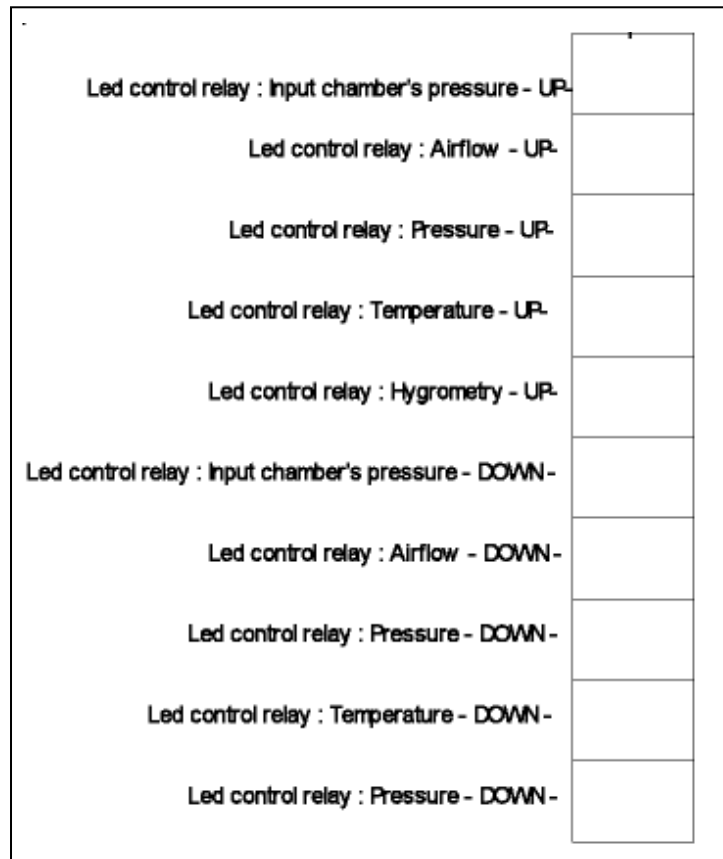
**Phase controllers and corresponding fuses:**



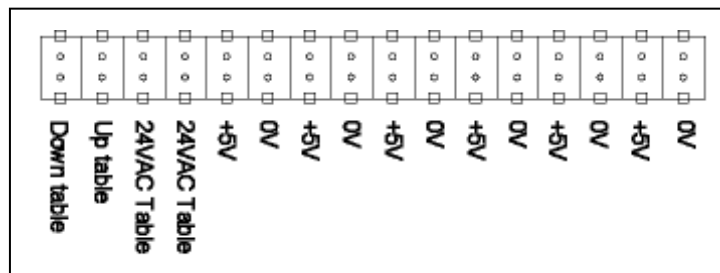
**+24V and +5V supplies, main filter :**



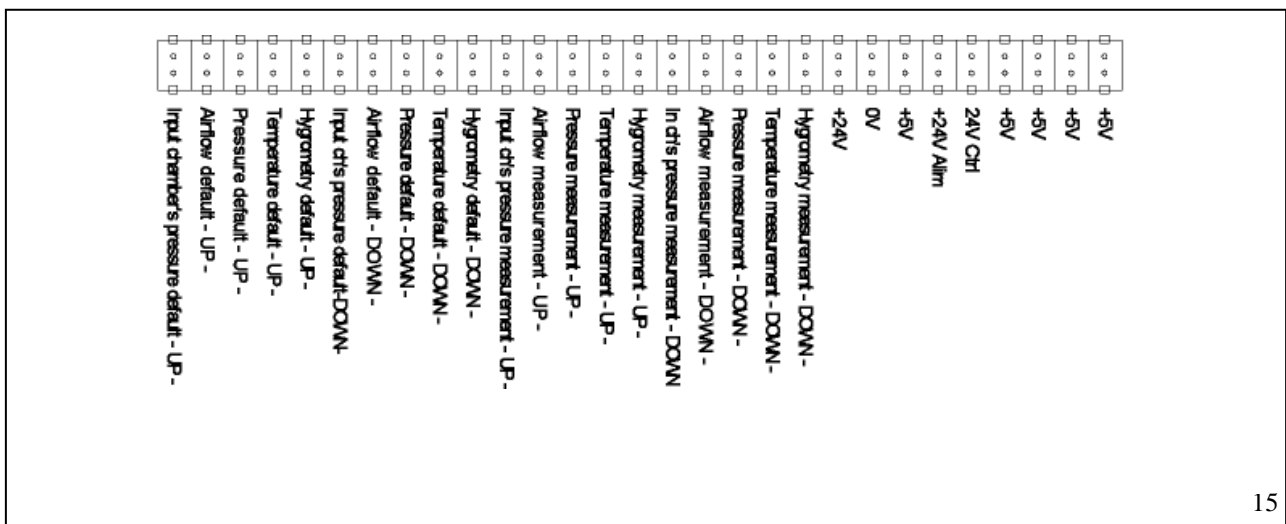
**Control relays :**



**Top left connectors :**



**Top right connectors :**





**List of fuses:**

Fuses inside the control compartment

<b>Fuses</b>	<b>Characteristics</b>	<b>References</b>
Fuse F2	5 x 20mm – 630 mA	A000789
Fuse F3	5 x 20mm – 630 mA	A000789
Fuse F4	5 x 20mm – 630 mA	A000789
Fuse F5	5 x 20mm – 630 mA	A000789
Fuse F6	5 x 20mm – 630 mA	A000789
Fuse F7	5 x 20mm – 630 mA	A000789
Fuse F8	5 x 20mm – 100mA	A000790

Main fuse :

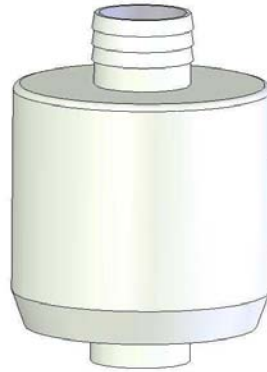
<b>Fuse</b>	<b>Characteristics</b>	<b>References</b>
Fuse F1	5 x 20mm – 4A	A000791



### **3.2 FILTERS :**

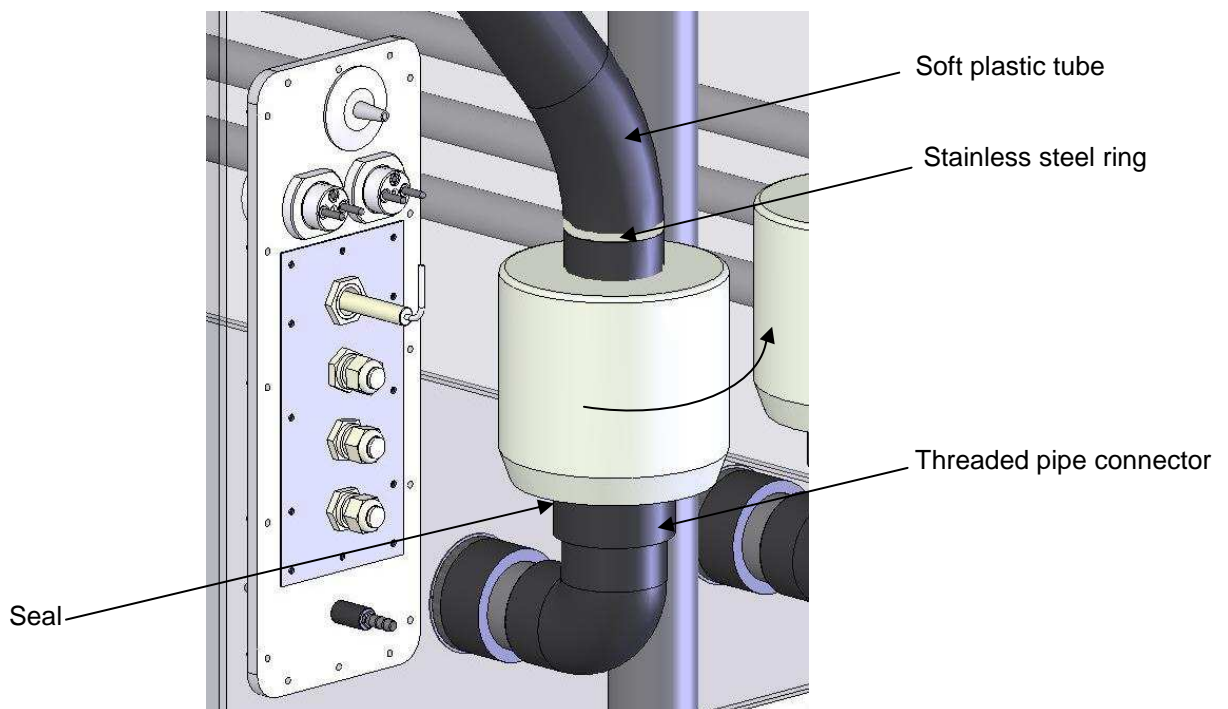
#### **Filter characteristics :**

The filters installed are "H13 BAG" type filter (99.99% efficiency for 0,3µm particles). They feature an "hose barb" nozzle input and a threaded output.



#### **Filter removal :**

1. Switch off the unit and unplug the equipment from mains.
2. Unscrew the stainless steel ring.
3. Remove the plastic tube from the filter nozzle.
4. Firmly grip the filter and unscrew it from the threaded pipe connector.



#### **Filter installation :**

1. Screw the new filter into the threaded connector.
2. Firmly screw it, in order to squeeze the round plastic seal, insuring absolute tightness.
3. Position the plastic tube onto the filter nozzle. To achieve this, use a fan heater to soften the plastic tube.
4. Screw the stainless steel ring.

### **3.3 FANS :**

#### **Fan characteristics :**

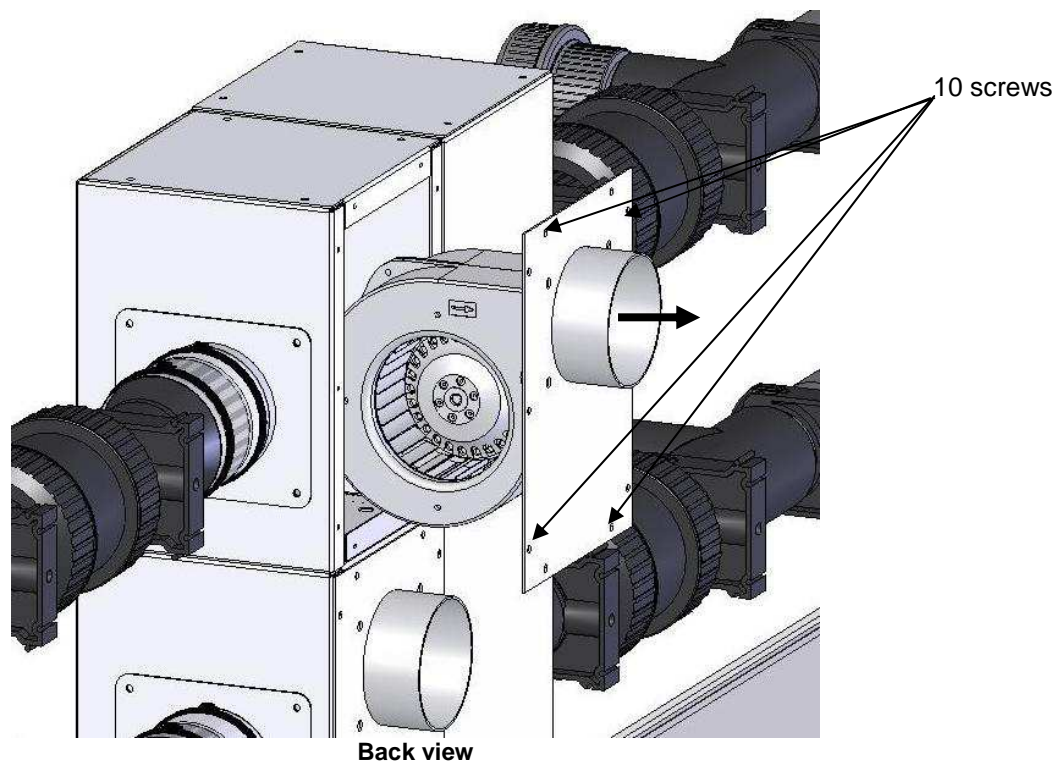
The fans installed are EBM PAPST G2E120 – AR77 - 01.

Each fan is connected to a panel and installed in a fan compartment.

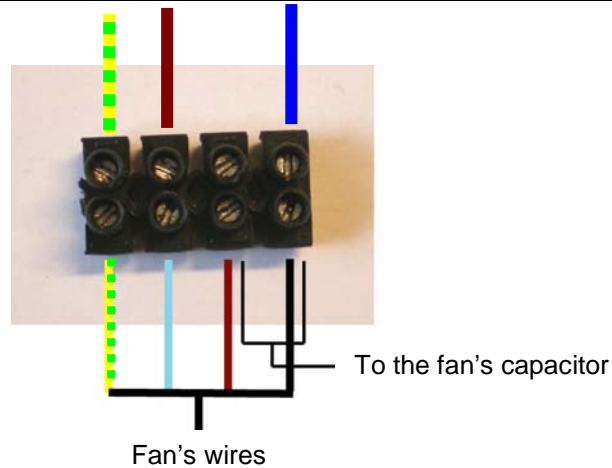


#### **Fan removal :**

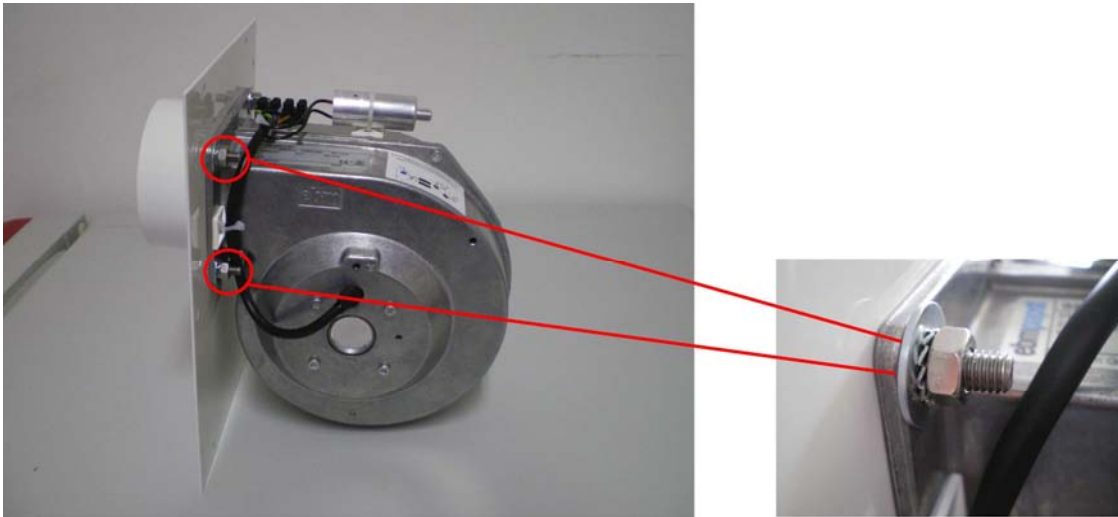
1. Switch off the unit and unplug the equipment from mains.
2. Unscrew the 10 locking screws. (H4 Head screw – 7 mm wrench).
3. Remove the fan together with the fan compartment panel, as described above.



4. Disconnected the 3 wire cable, connected to the fan.  
Brown : Live.  
Blue : Neutral.  
Yellow-Green : Earth.



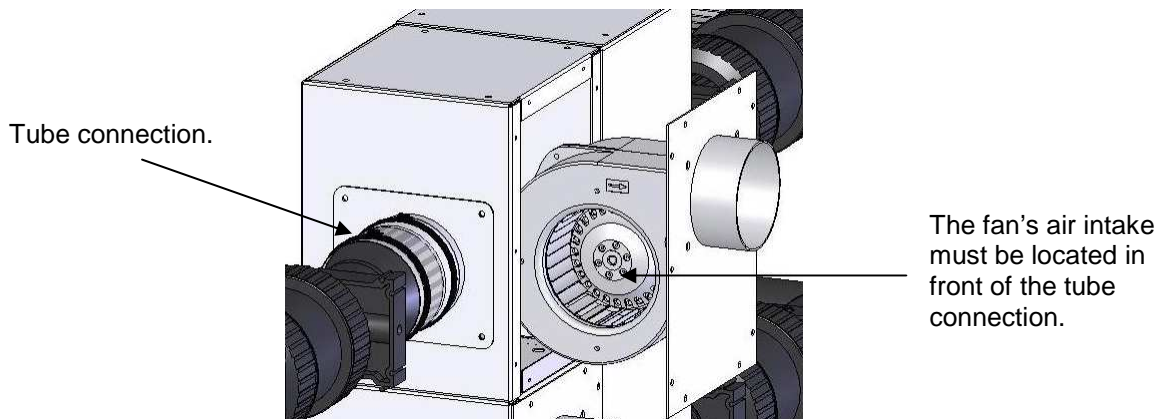
5. Remove the fan together with the compartment panel.
6. Remove the fan from the compartment panel :



Unscrew the 4 locking screws. (H6 Head screw – 10 mm wrench).  
Preserve the screws for fitting the new fan.

**Fan installation :**

1. Fit the new fan onto the compartment panel. Screw the 4 H6 head locking screws.
2. Connect the supply cable to the fan's connector. Follow the diagram displayed above.
3. Use tie raps to avoid the risk of accidentally stick the wires into the rotor.
4. Position the fan and panel into the compartment. Mind the vertical position of the fan :



5. Screw the 10 locking screws of the fan's compartment panel (H4 Head screw – 7 mm wrench) .

**CHAPTER 4 :**  
**CONSUMABLES LIST**

<b>Reference</b>	<b>Designation</b>
A000357	Shoulders flat ring
A000044	Shoulder circle ring
A000036	Wrist circle ring
A000019	Jersey sleeve, with PVC coating
A000120	Wrist cylinder
A000354	Pair of neoprene gloves – Size : 6 – Width. : 0.45mm
A000314	Pair of neoprene gloves – Size : 7 – Width. : 0.45mm
A000355	Pair of neoprene gloves – Size : 8 – Width. : 0.45mm
A000356	Pair of neoprene gloves – Size : 9 – Width. : 0.45mm
A000009	50m <sup>3</sup> BAG Filter(For isolators)
A000374	50m <sup>3</sup> BAG Filter (For containers)
A000216	Mini-filter used for the manometer and probe (threaded)
A000043	Mini-filter used for the manometer and probe (fluted)
T000003	Round pre-filter, Ø150 mm
A000213	PVC sleeve, Ø90mm (To connect Ø63mm tubes to the fan compartment)
T000002	Circle ring, for a Ø400mm back service port
T000004	Circle ring, for a Ø500mm back service port
T000005	Circle ring, for a Ø600mm back service port



# MAINTENANCE MANUAL I-BOX ESA Barcelona

N° doc : 50030

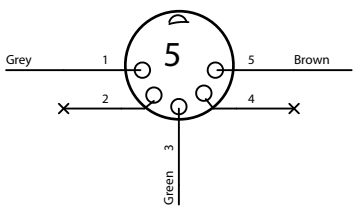
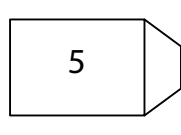
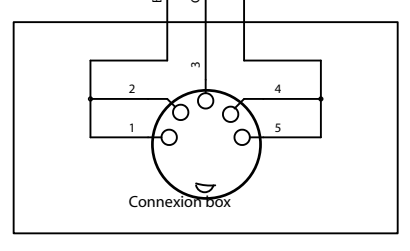
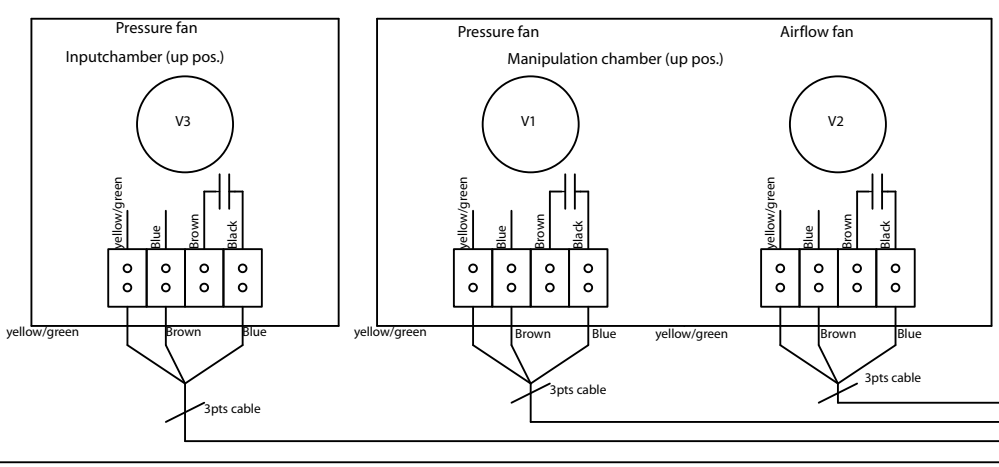
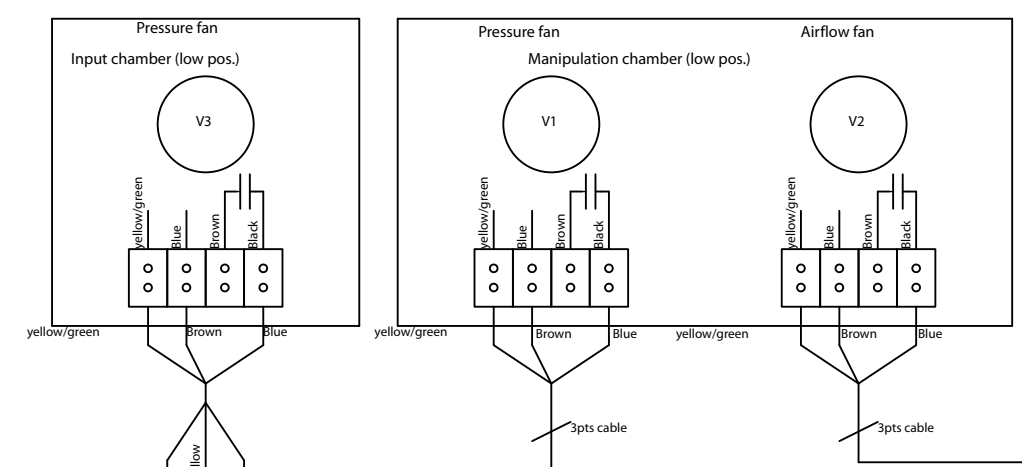
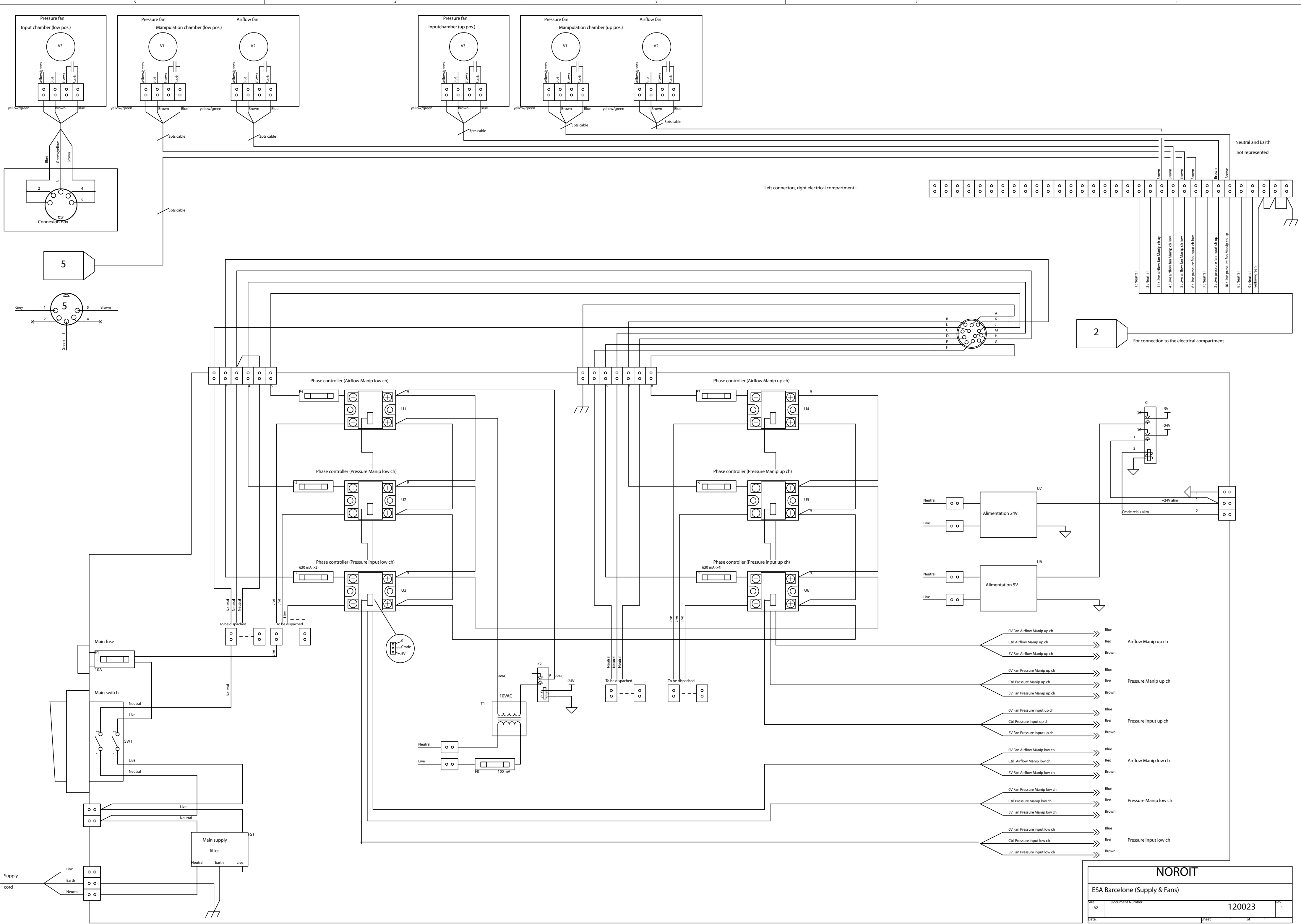
Index : A

## 10 ADDENDUM :

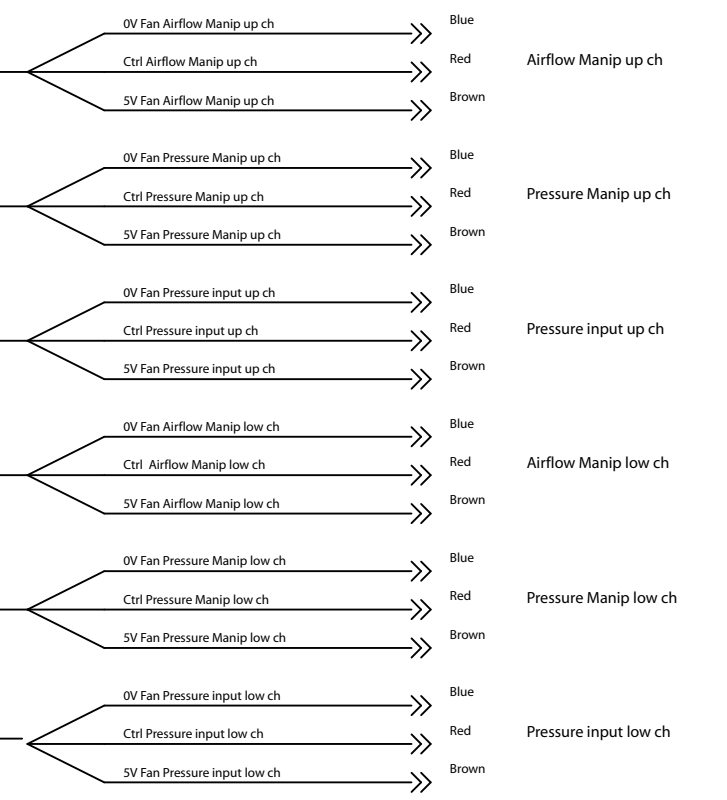
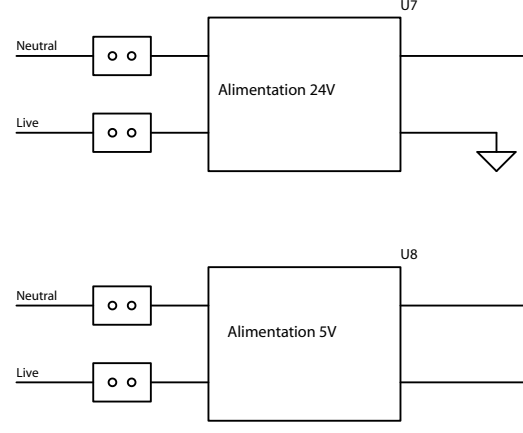
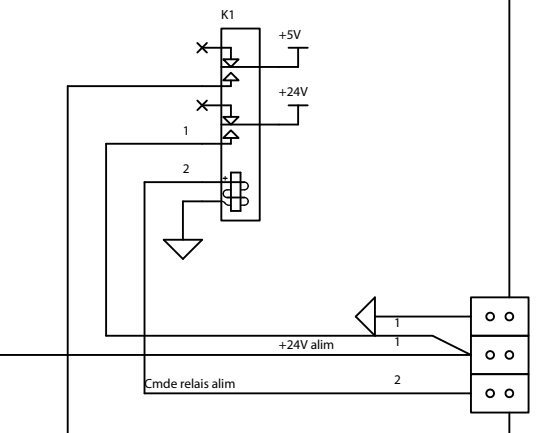
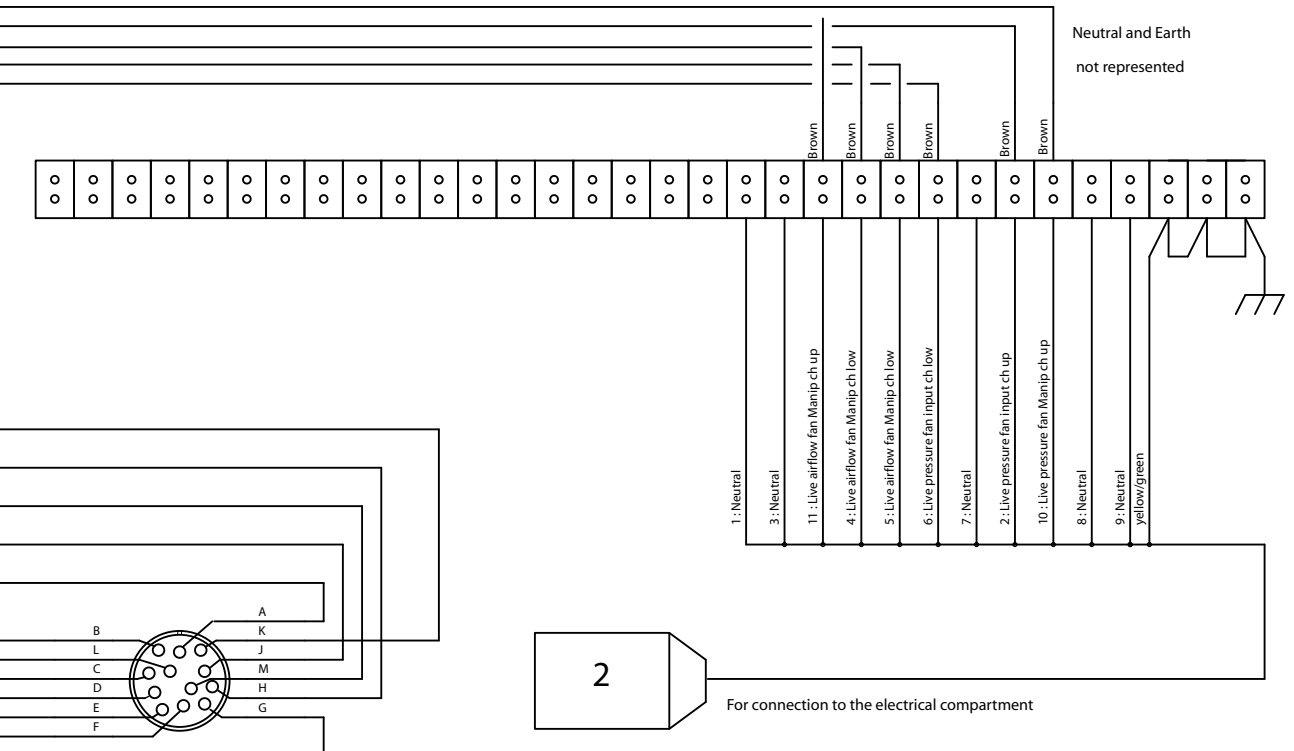
- Addendum I                      Electrical diagrams
- Addendum II                     Mechanical diagrams

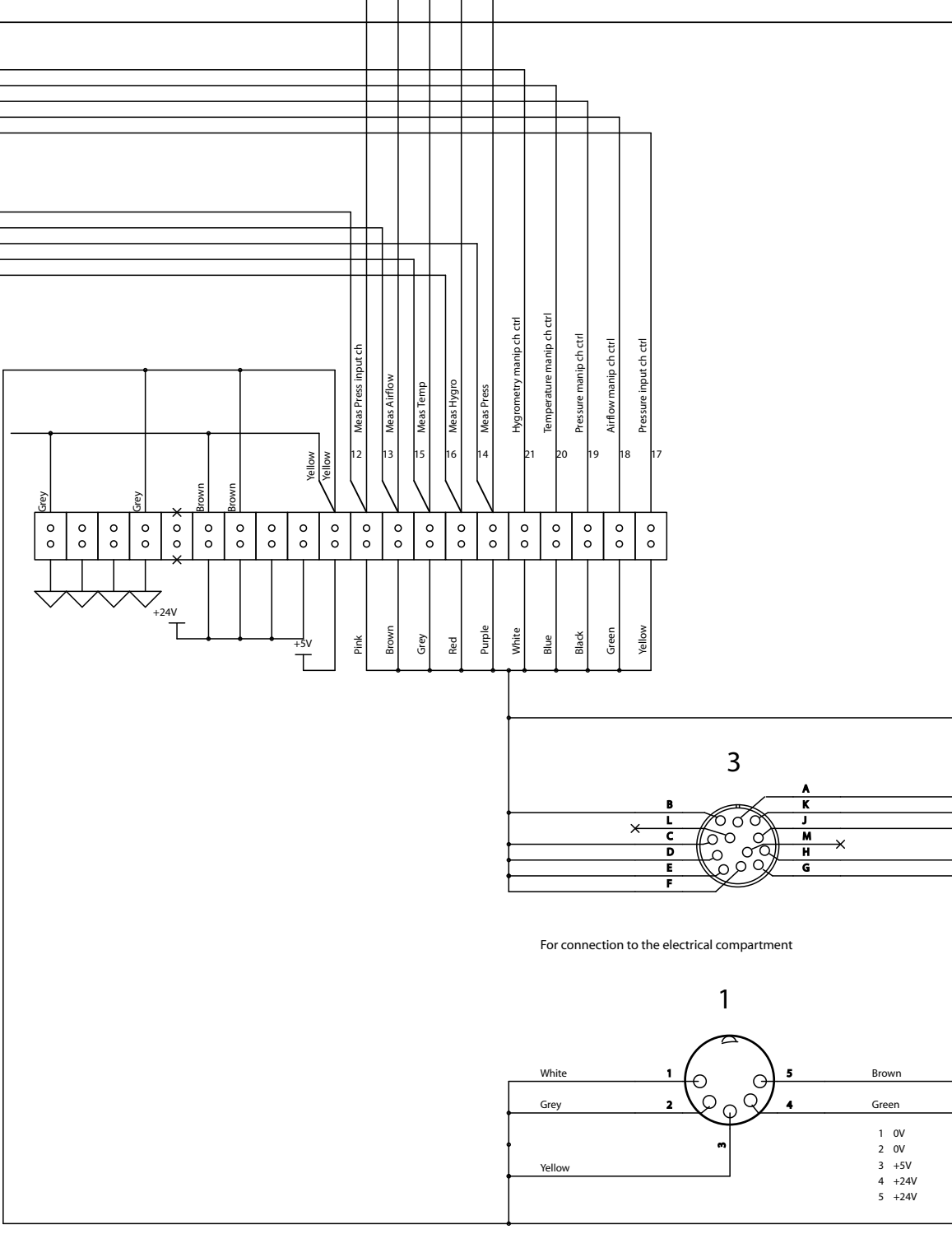
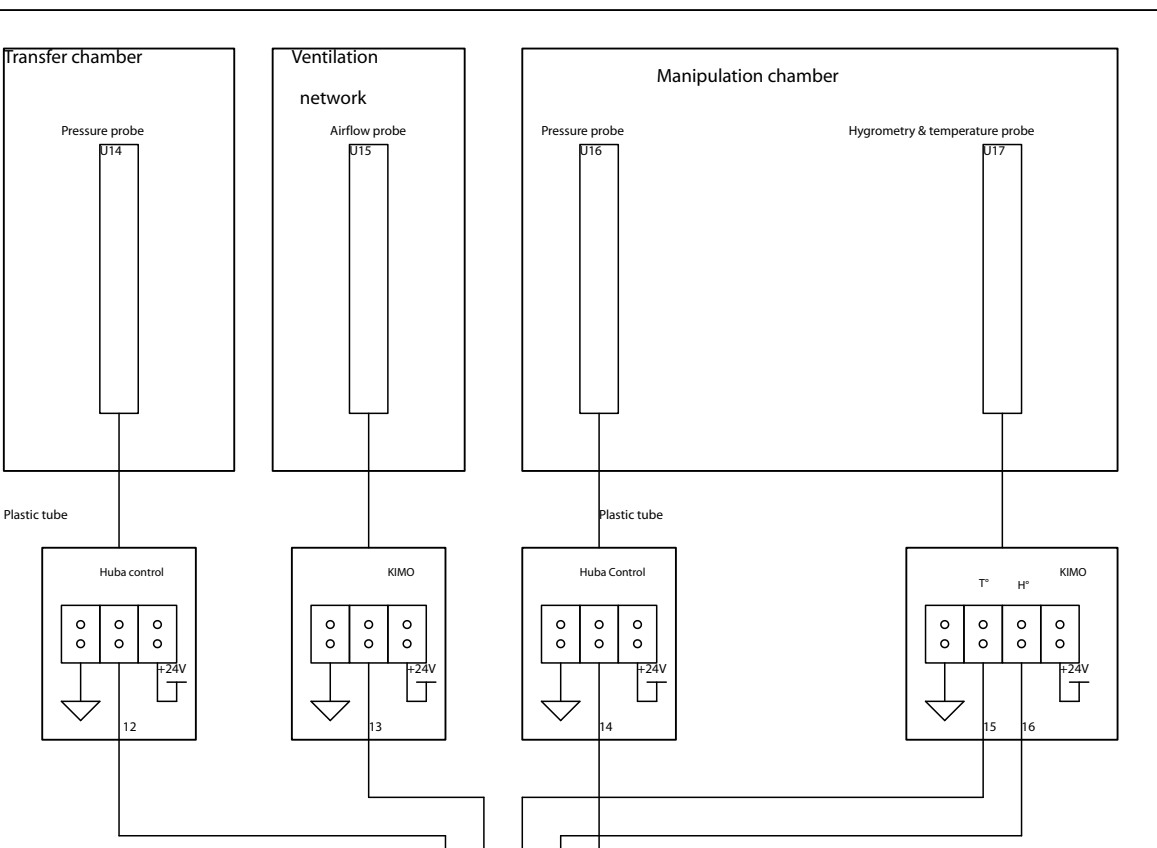
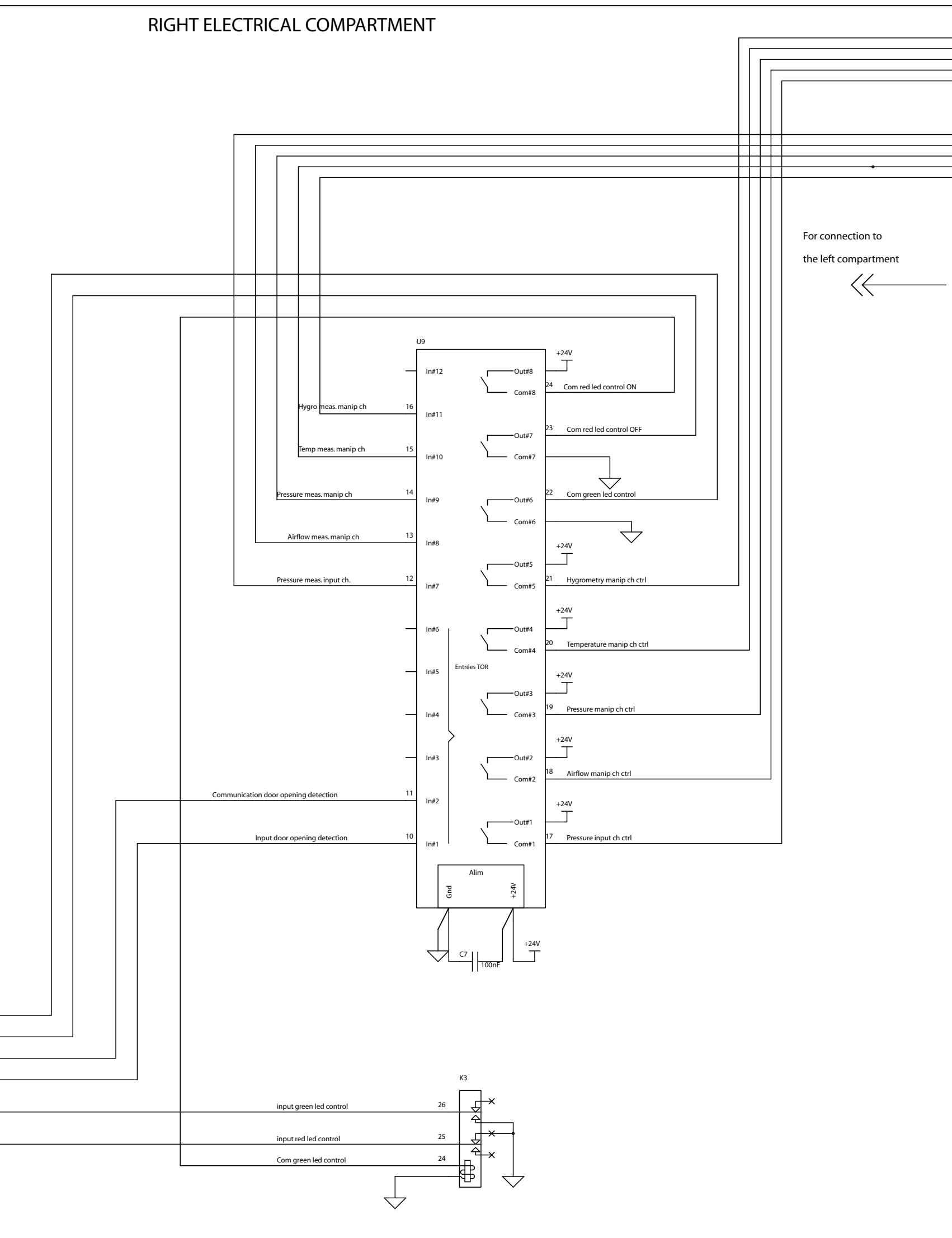
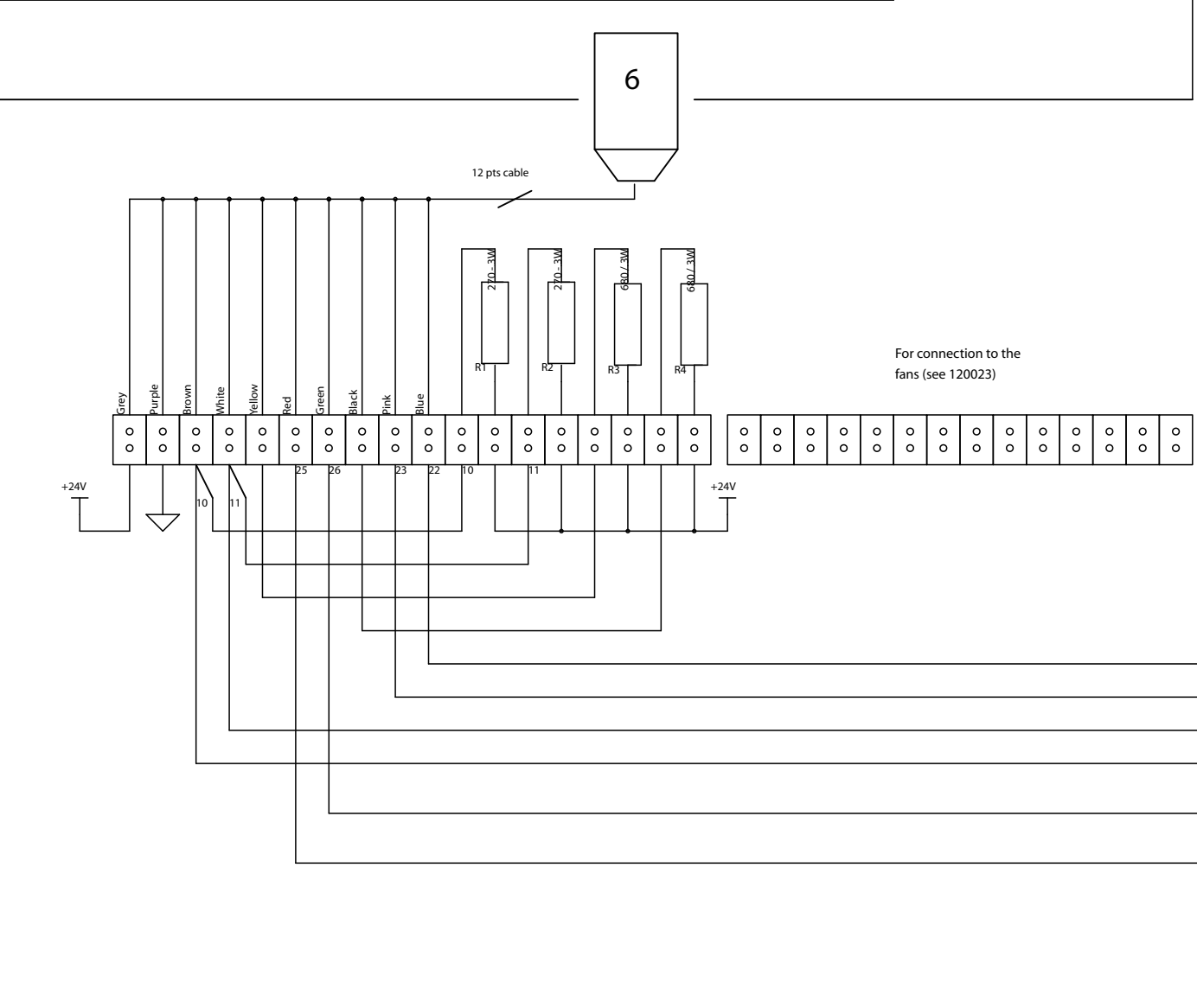
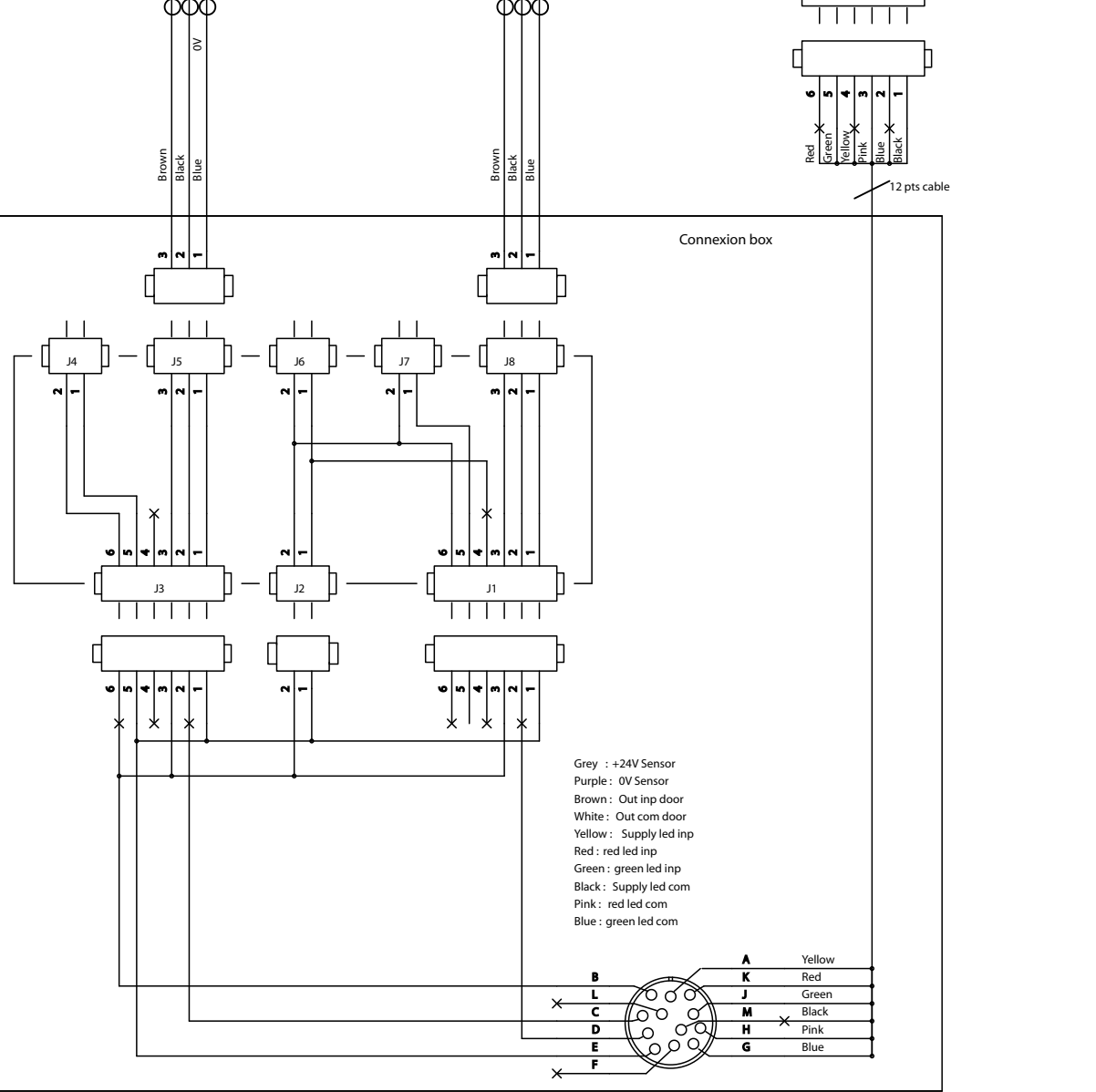
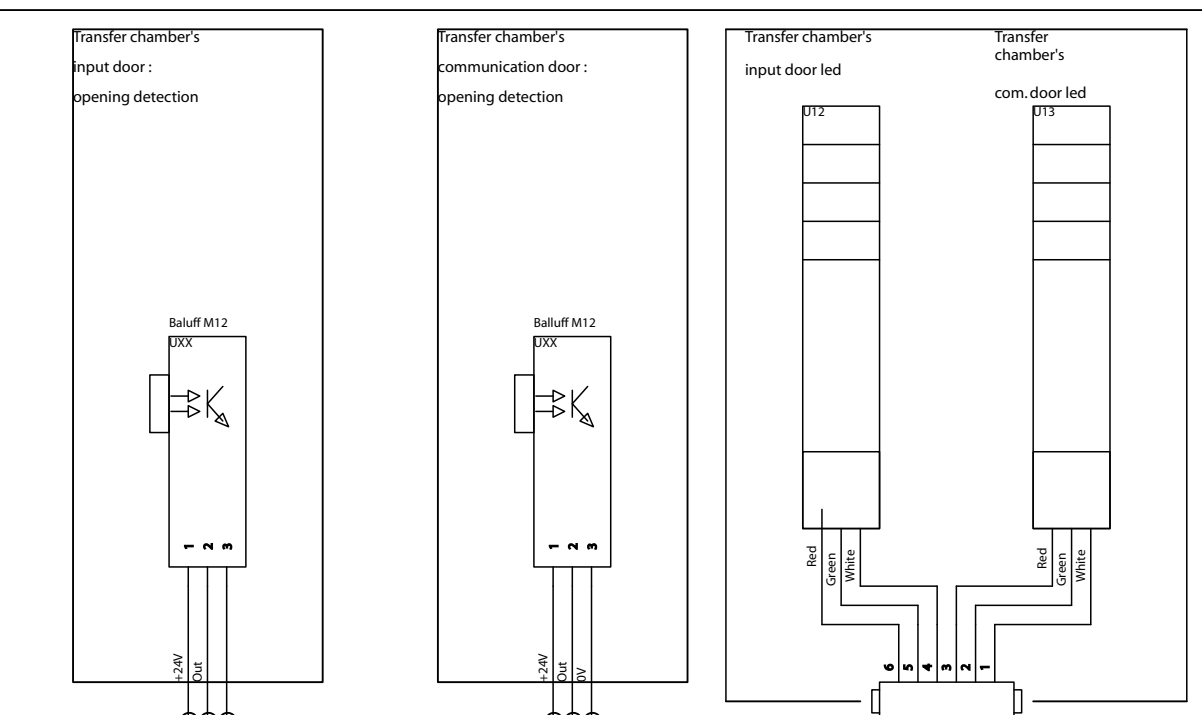


## 3. ELECTRICAL DIAGRAMS

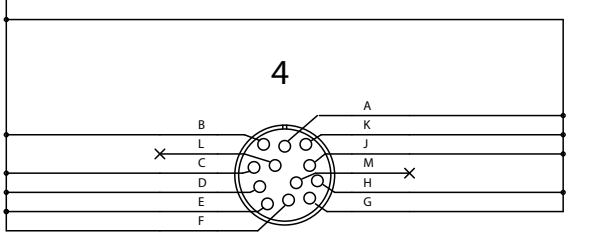
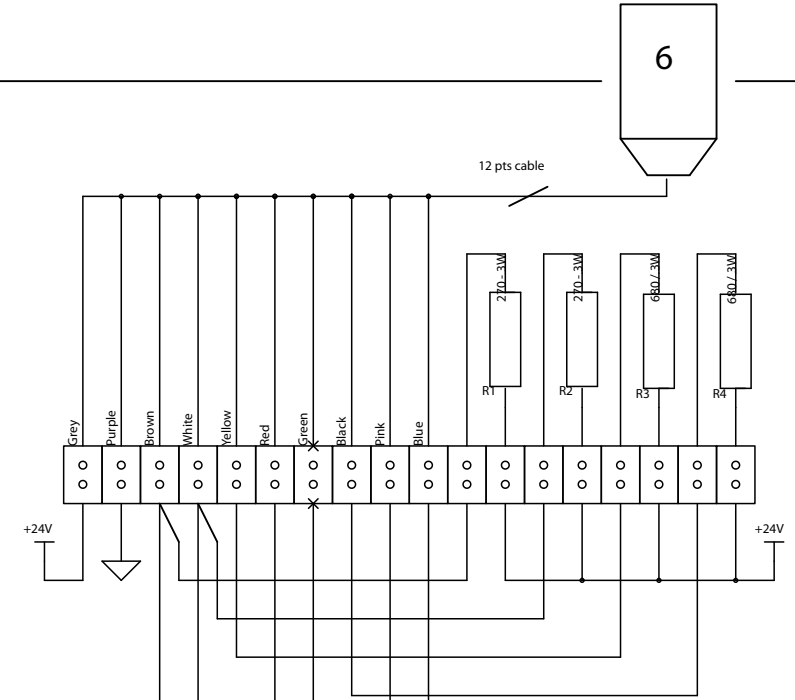
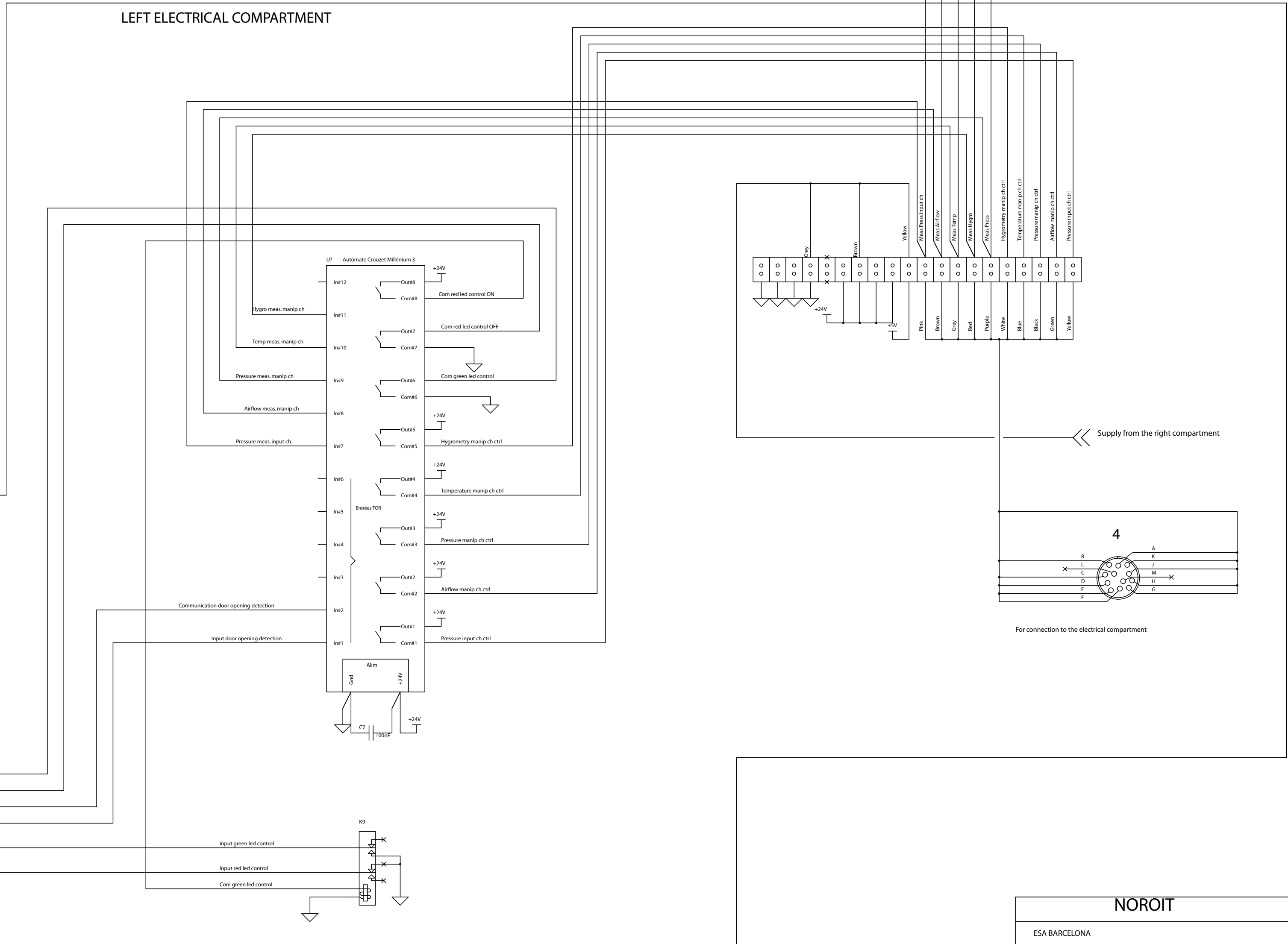
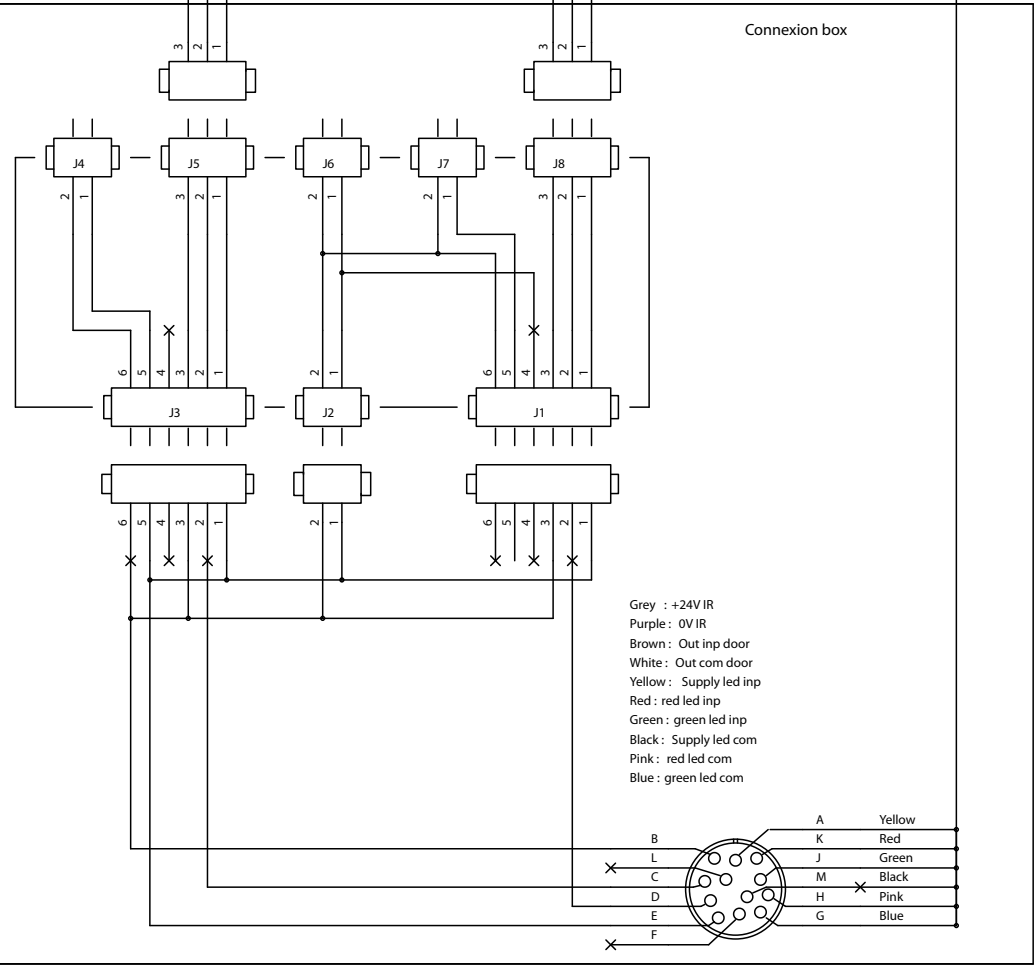
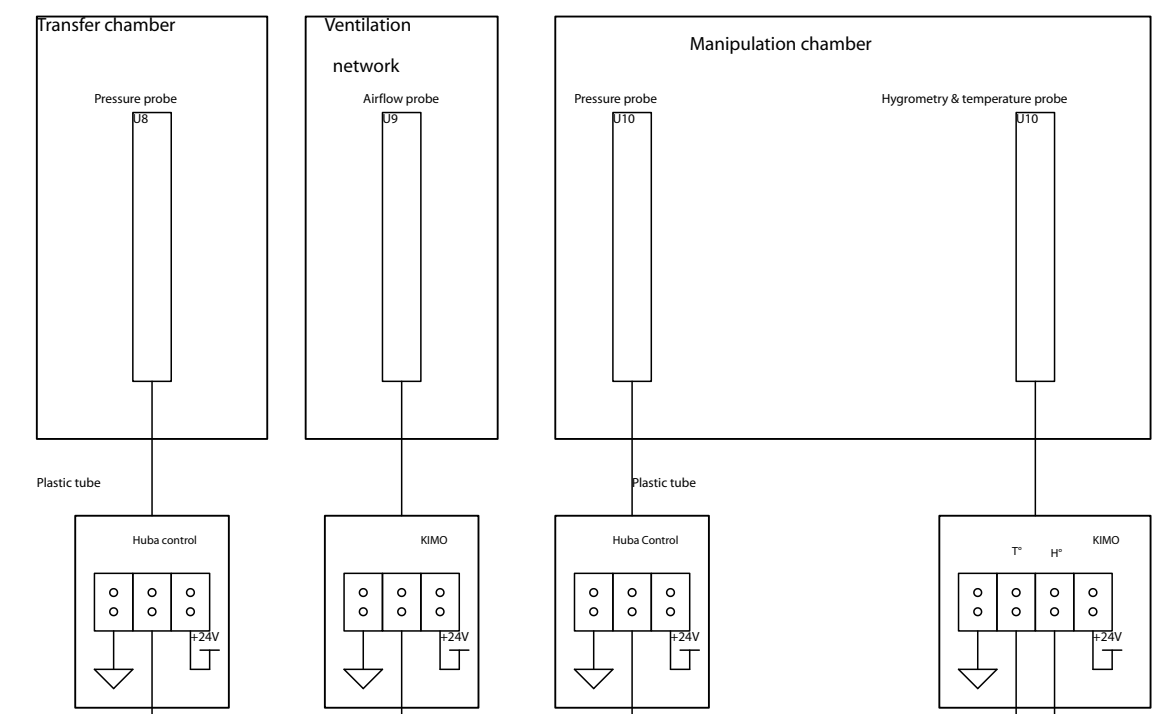
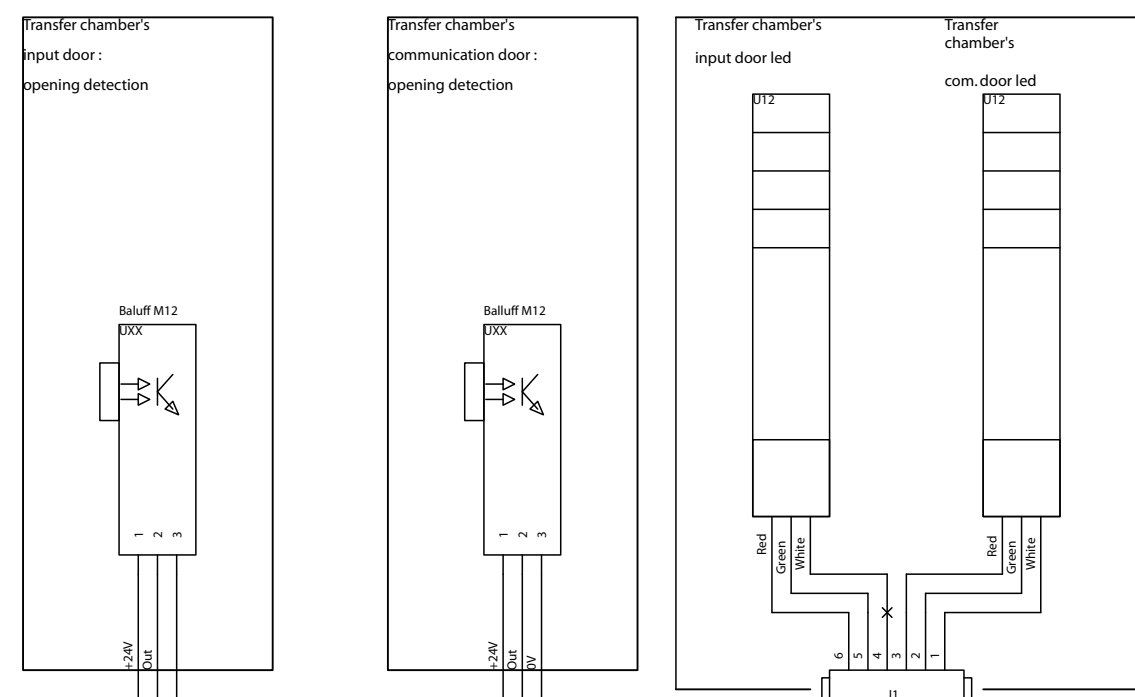


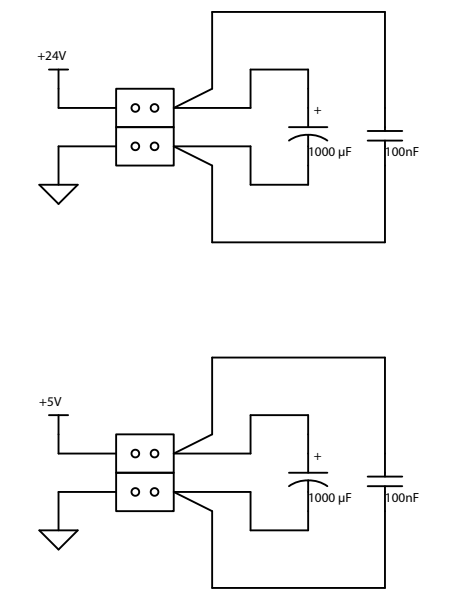
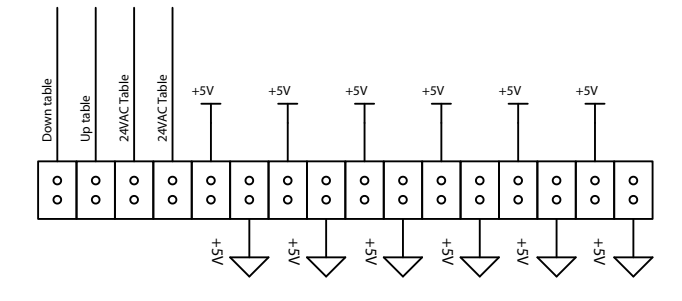
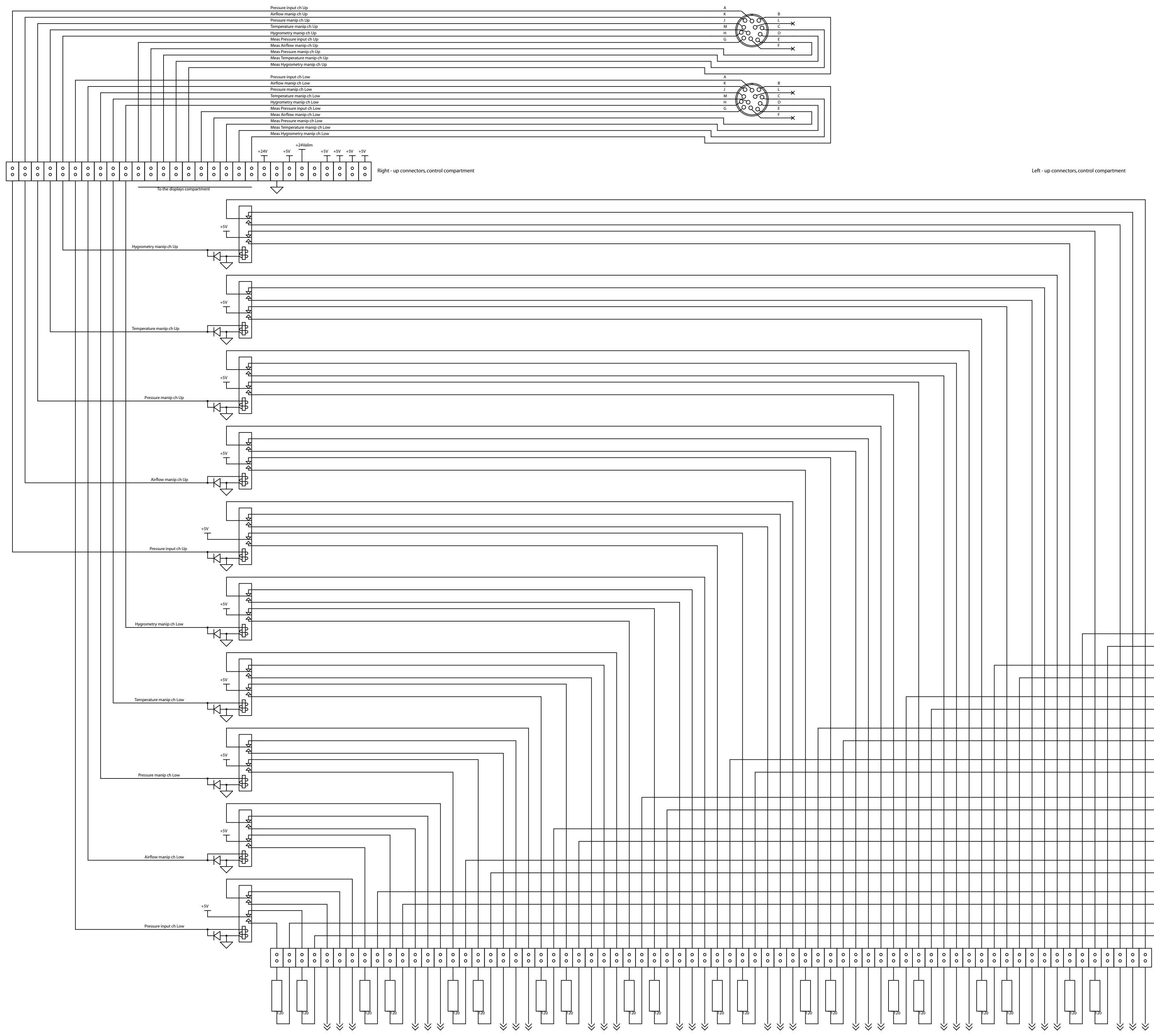
Left connectors, right electrical compartment :



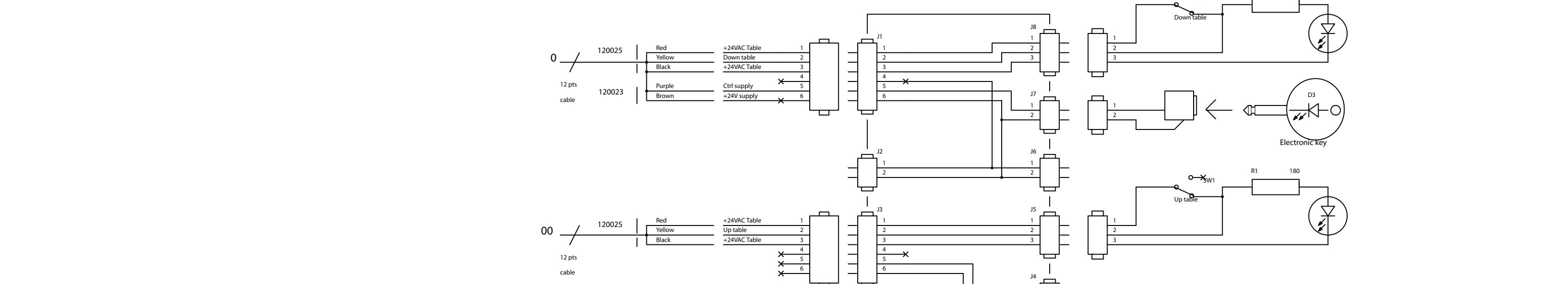
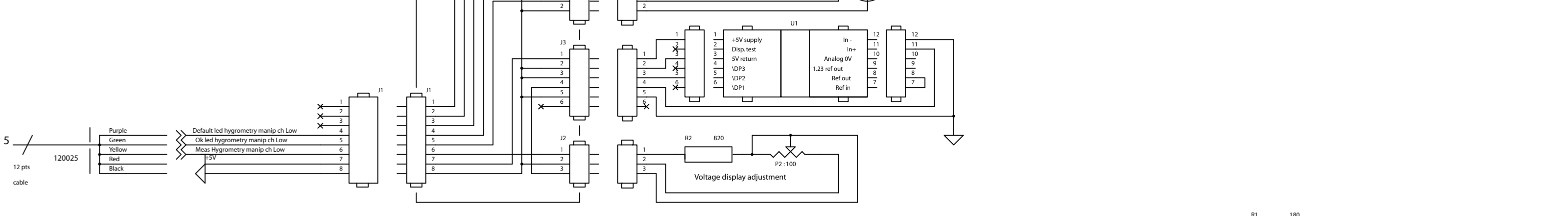
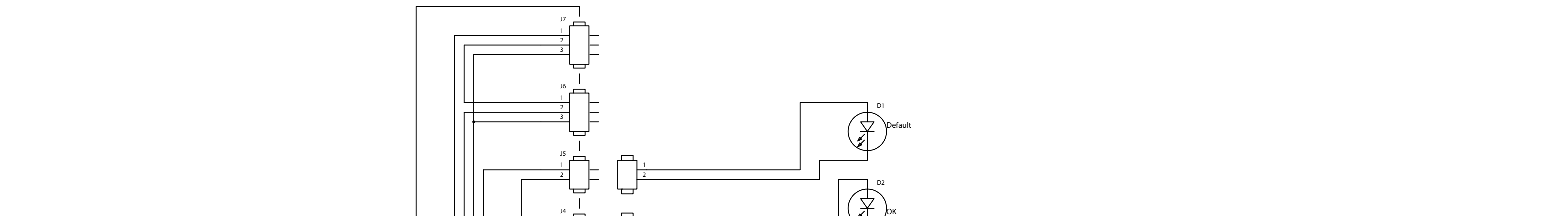
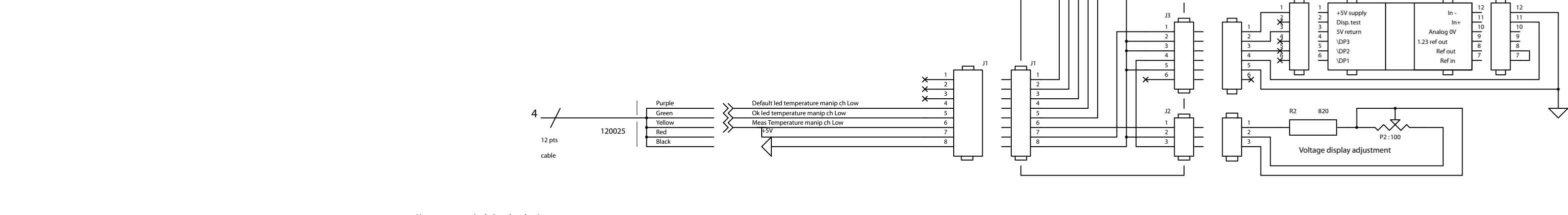
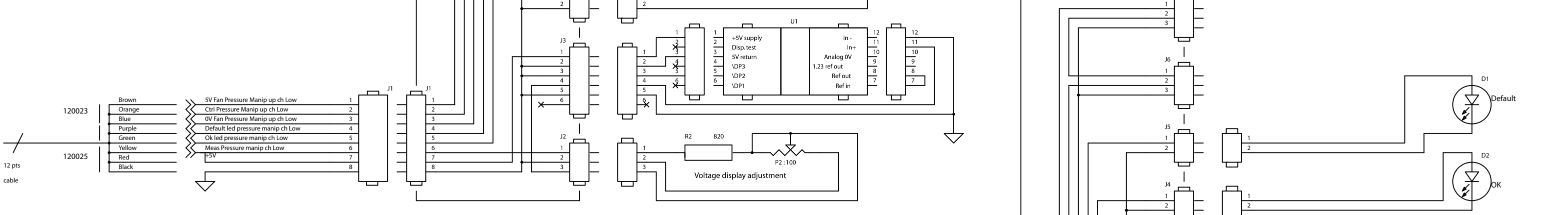
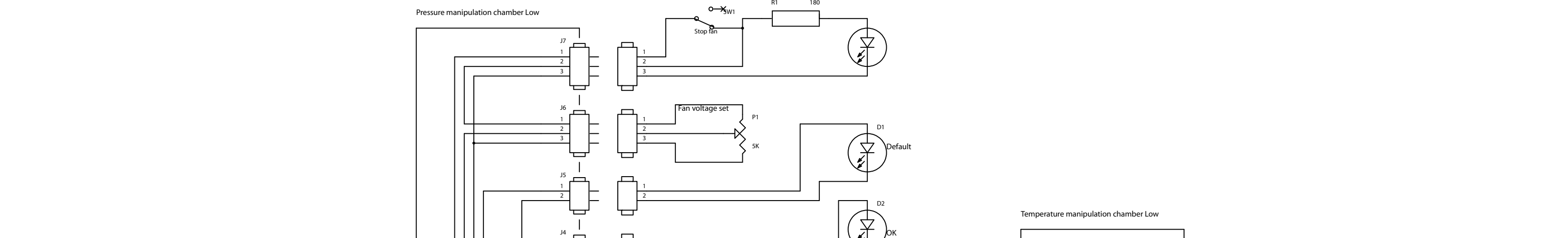
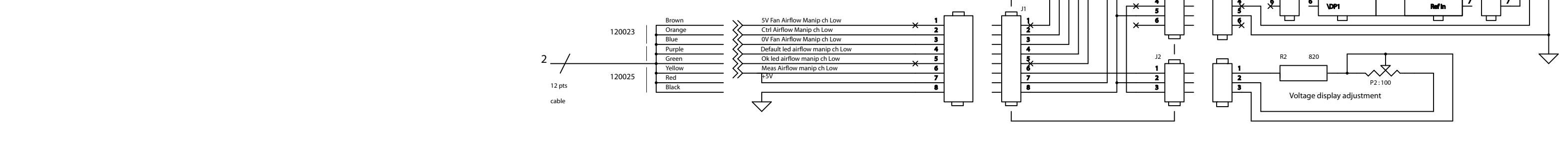
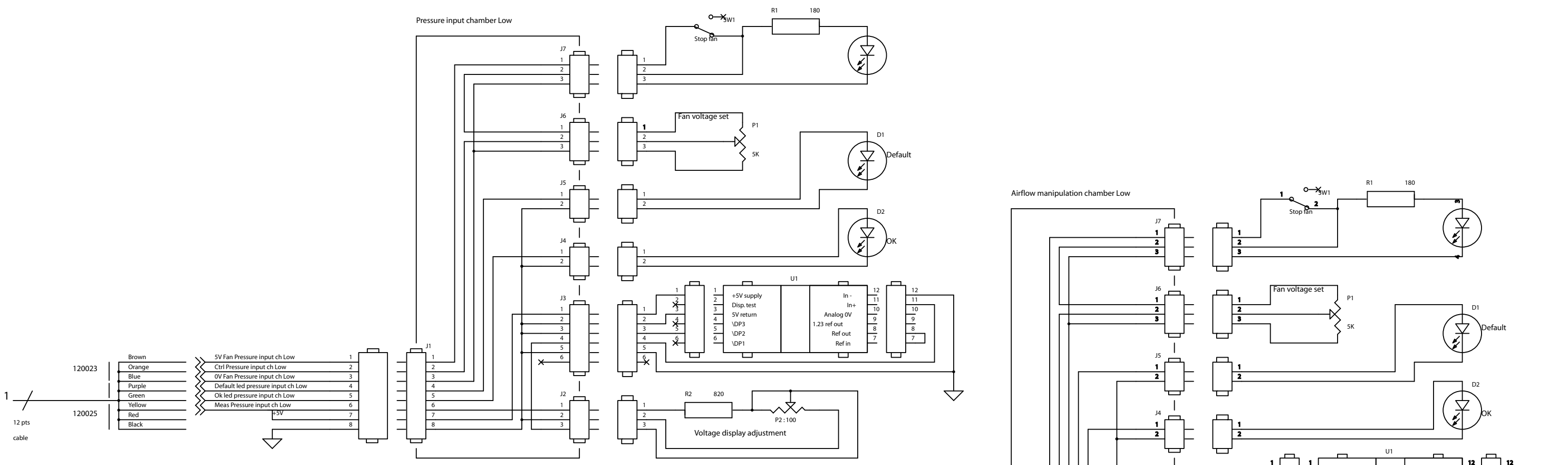


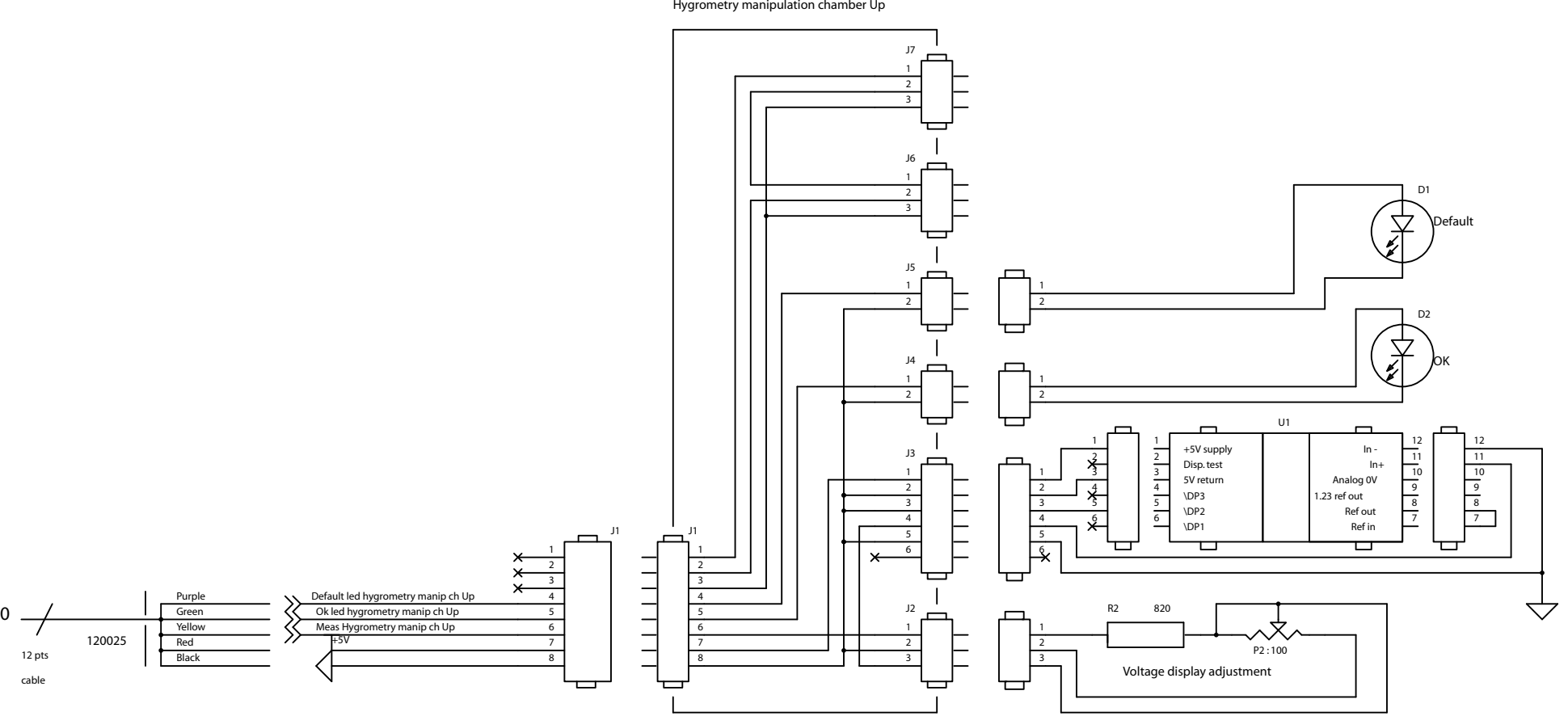
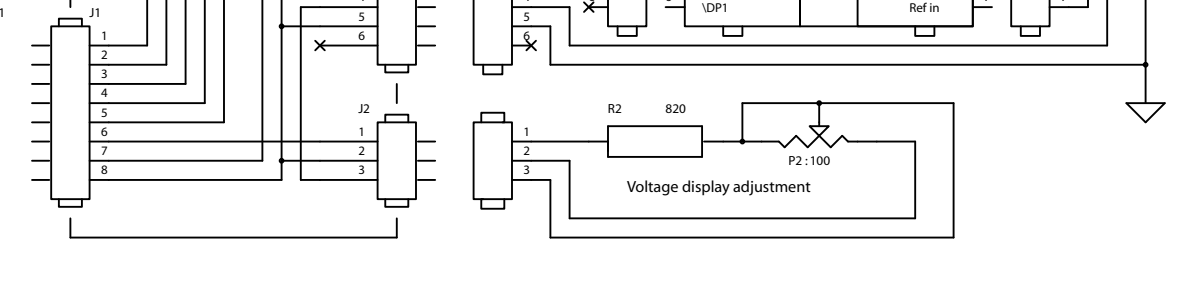
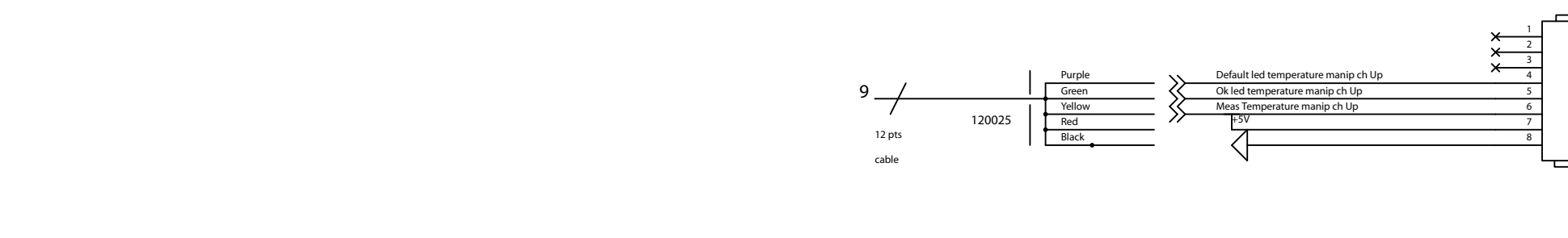
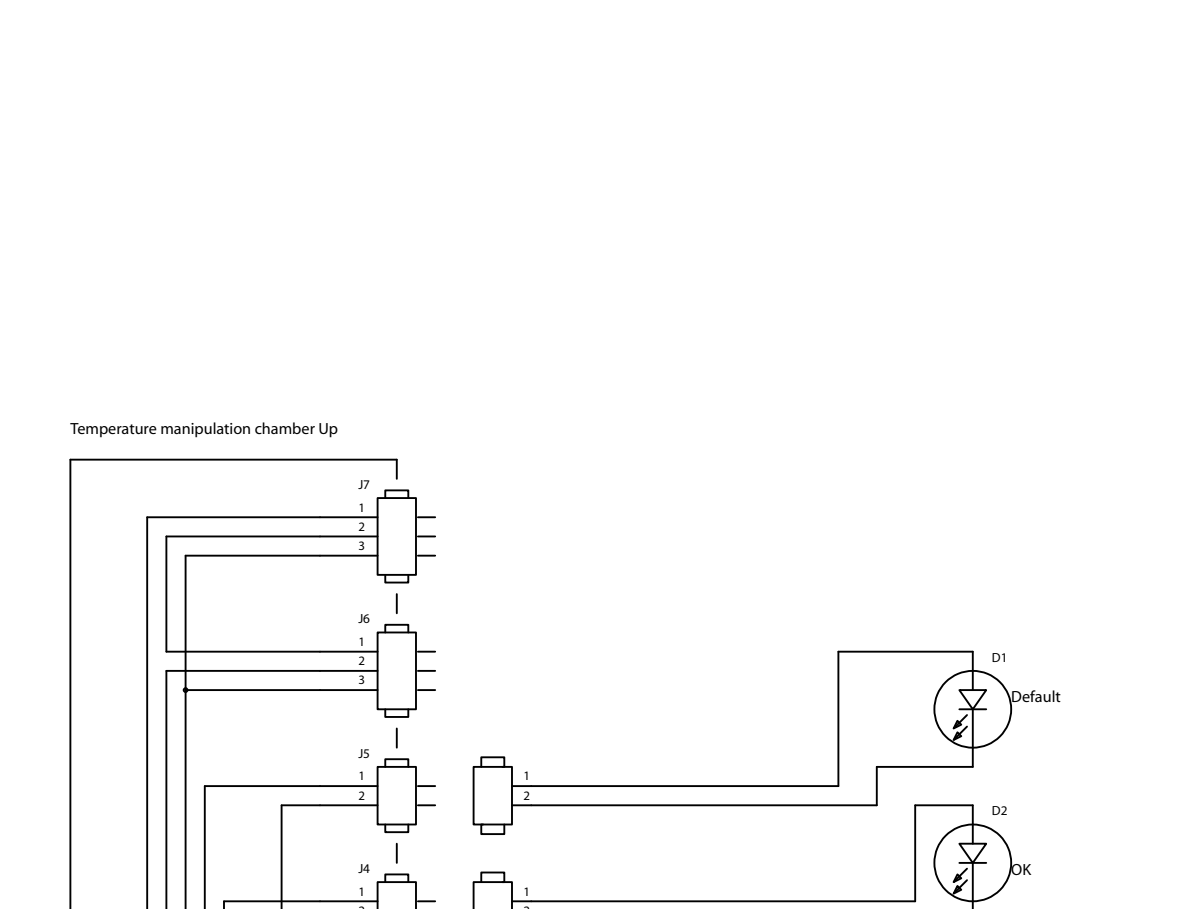
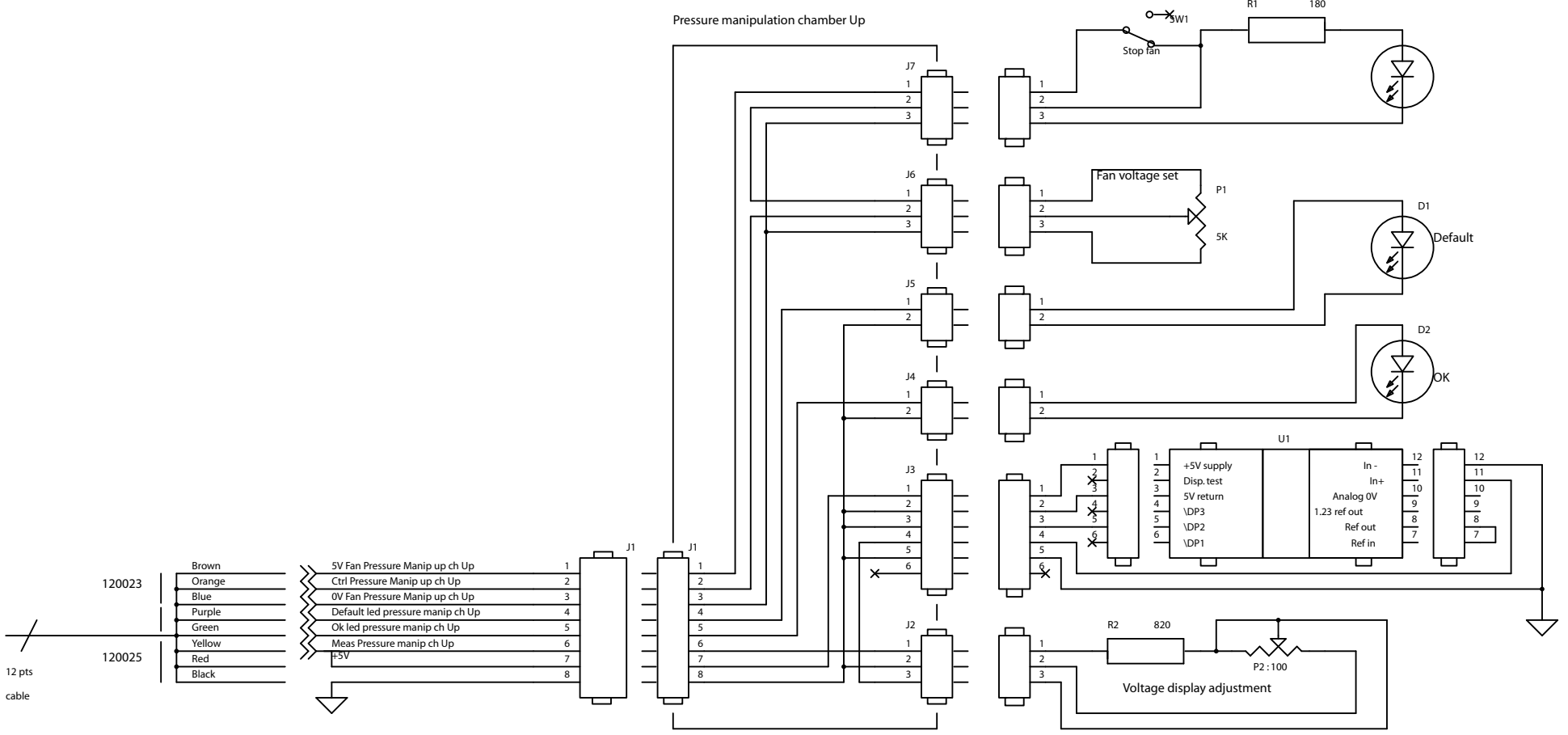
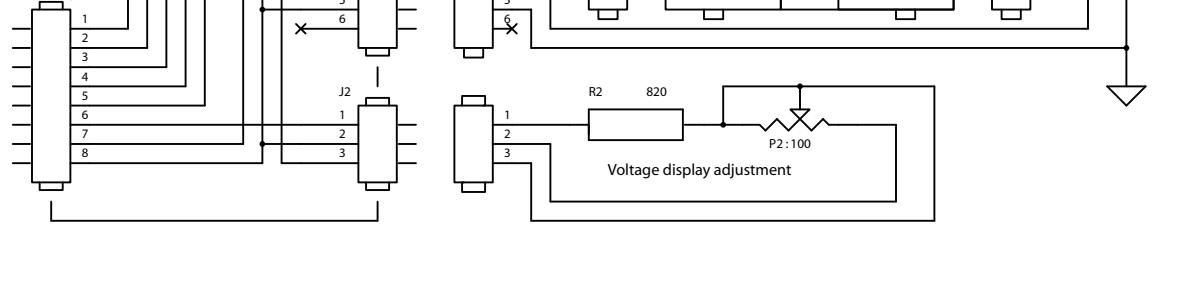
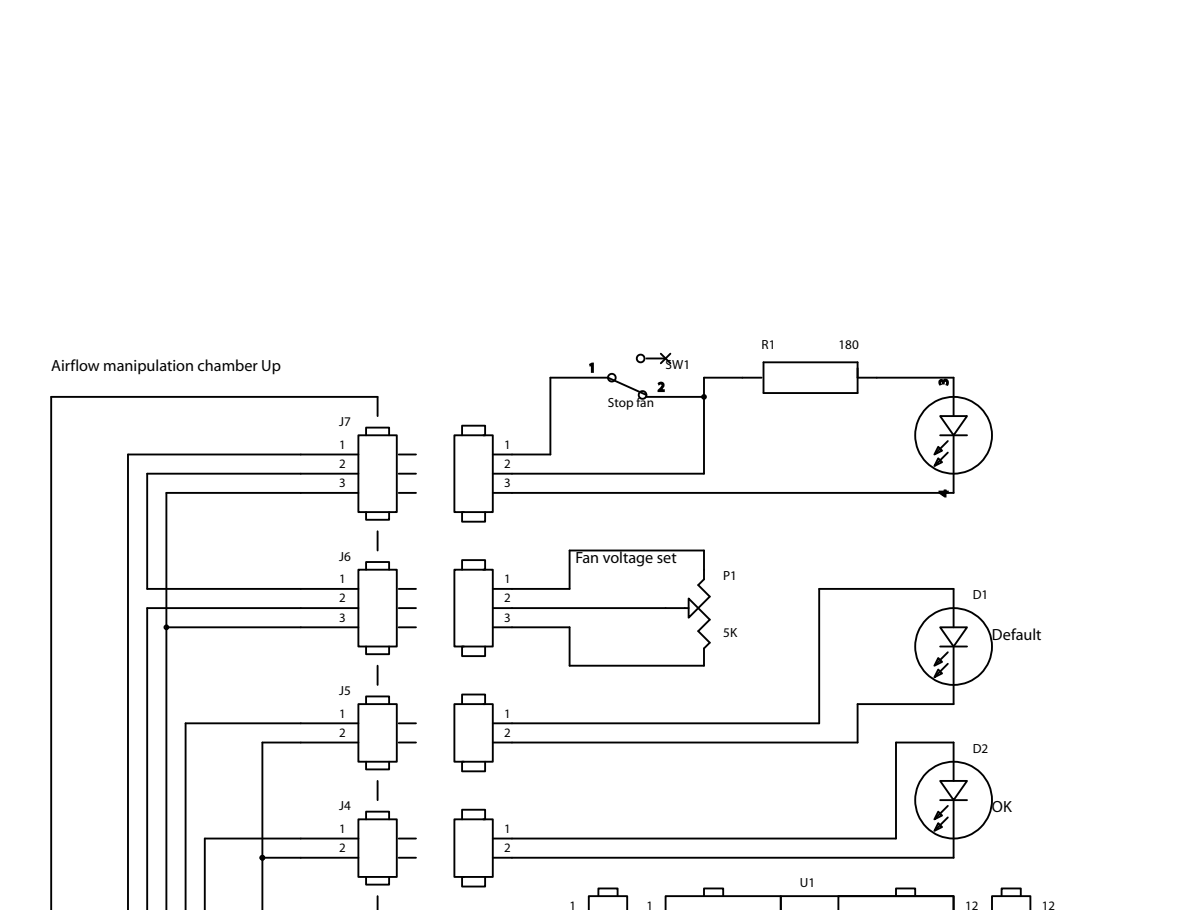
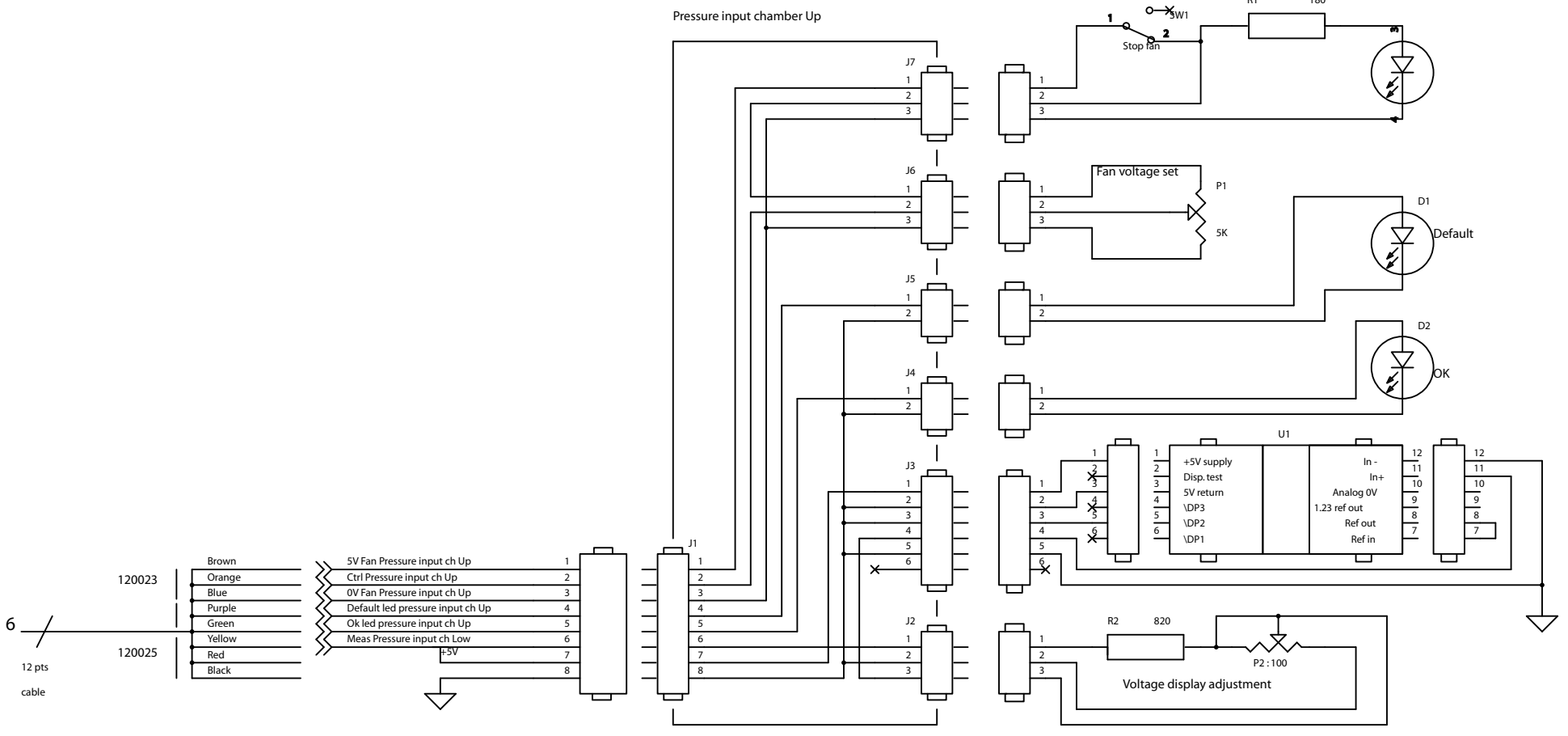




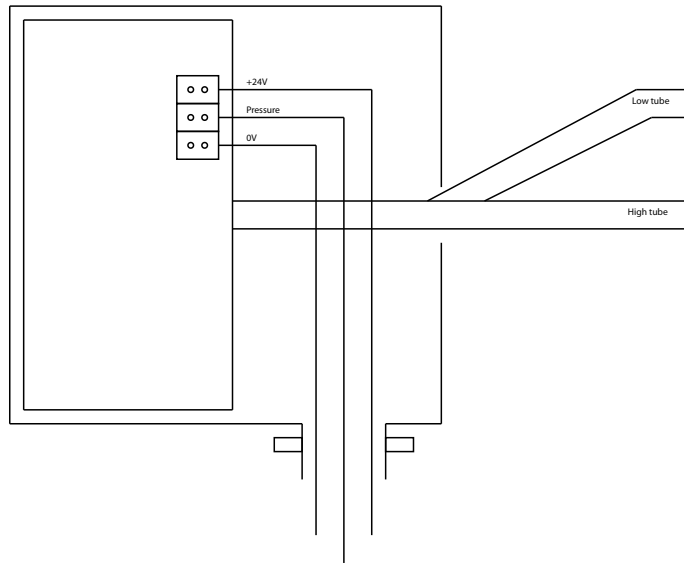


- Ok led hygrometry manip ch Up
- Default led hygrometry manip ch Up
- Ok led temperature manip ch Up
- Default led temperature manip ch Up
- Ok led pressure manip ch Up
- Default led pressure manip ch Up
- Ok led airflow manip ch Up
- Default led airflow manip ch Up
- Ok led pressure input ch Up
- Default led pressure input ch Up
- Ok led hygrometry manip ch Low
- Default led hygrometry manip ch Low
- Ok led temperature manip ch Low
- Default led temperature manip ch Low
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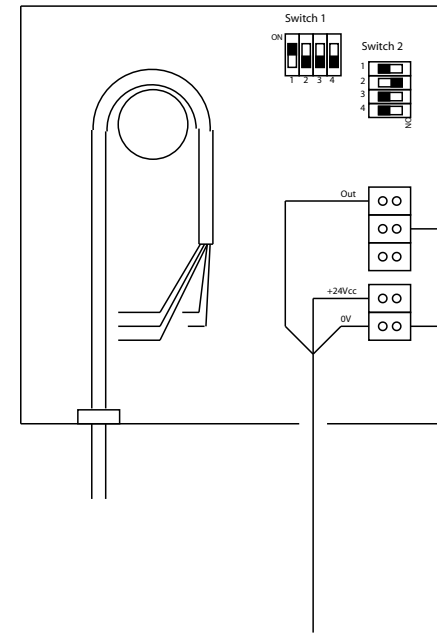




Pressure probe wiring : "HUBA CONTROL 694 - 300Pa"



Airflow probe wiring "KIMO CTV100"



**NOROIT**

Wiring of pressure and airflow transmitters

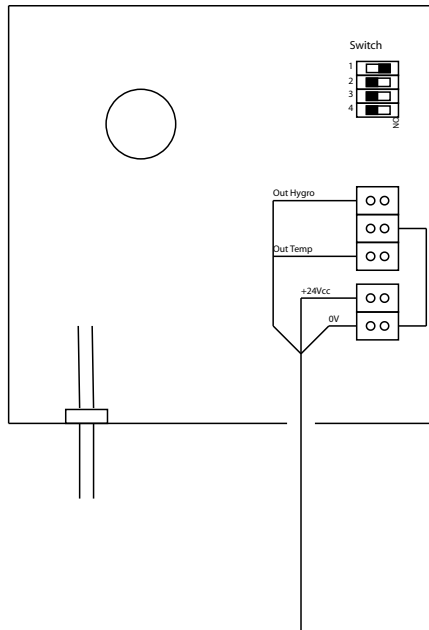
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Size A4	CAGE Code Julien VICTOR	DWG NO	Rev 1
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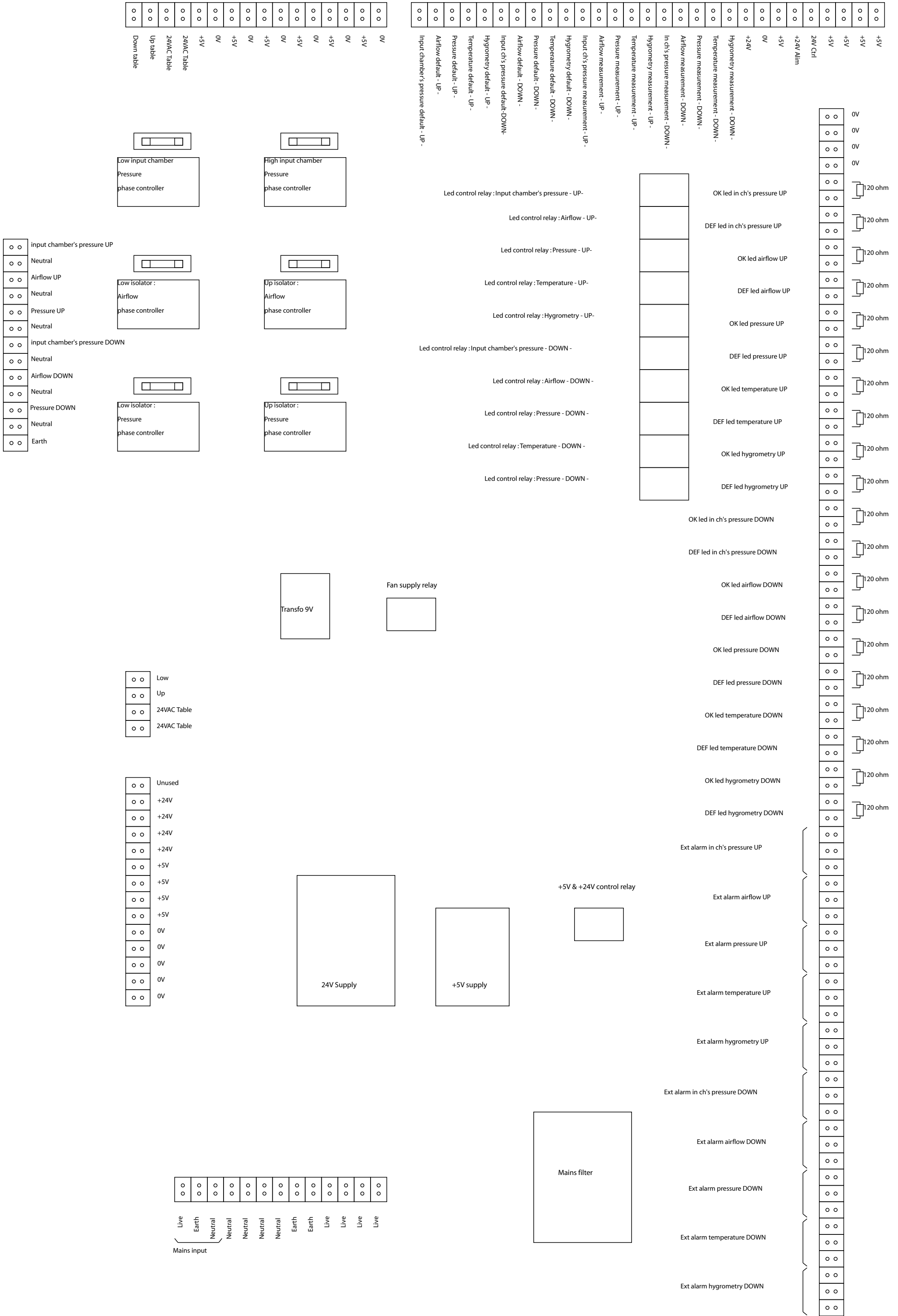
17/11/2006

Scale	Sheet 3 of 9
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Temperature and hygrometry probe wiring "KIMO TH100"



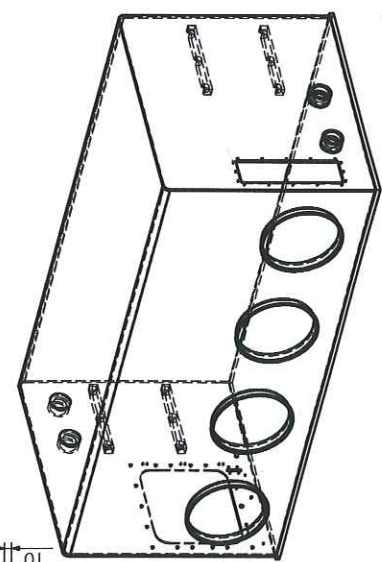
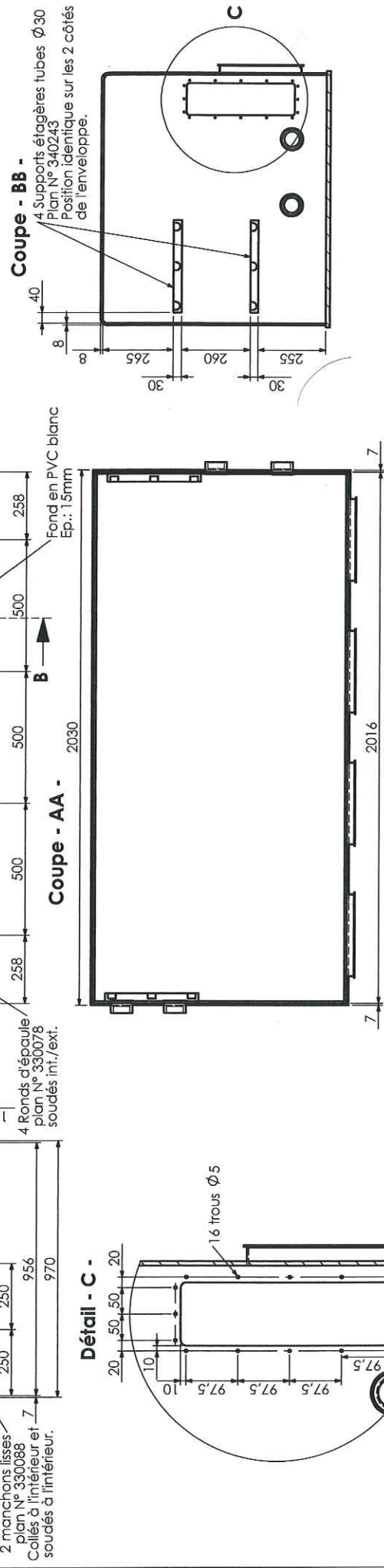
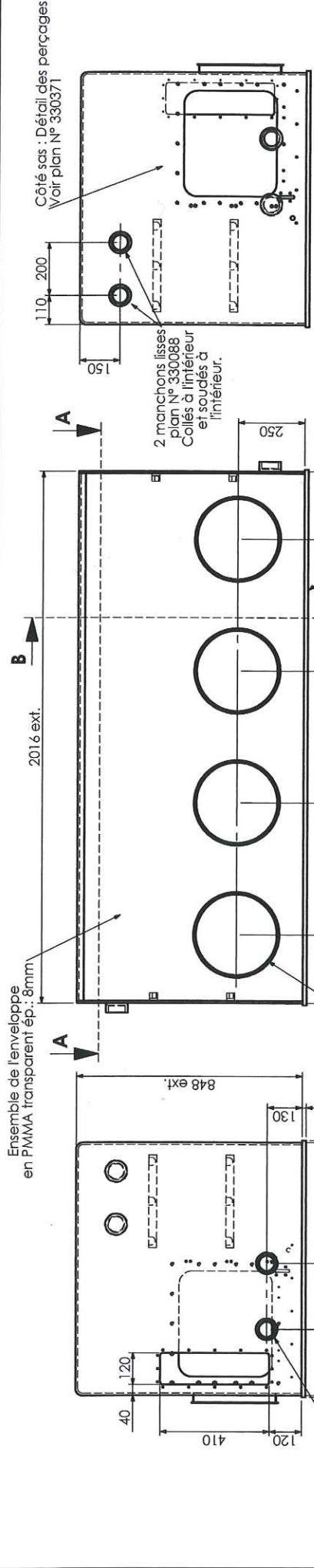
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<b>140011</b>	Size A4	CAGE Code Gilles MAHE	Rev 1
17/11/2006	Scale	Sheet 3 of 9	



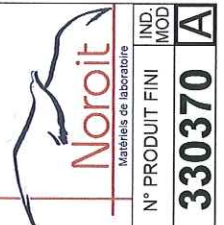


## 4. MECHANICAL DIAGRAMS



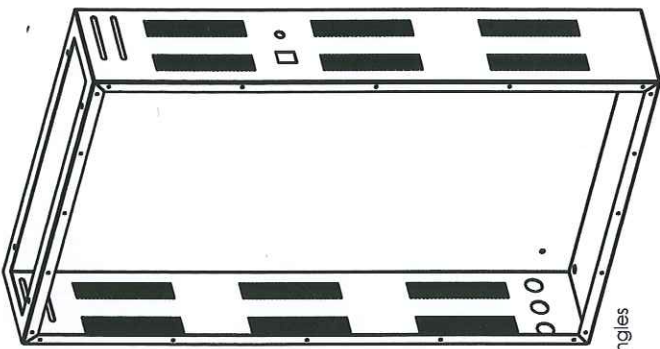
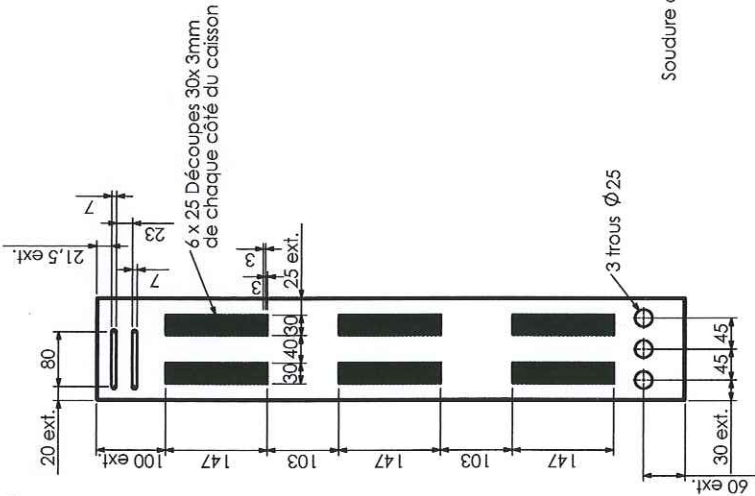
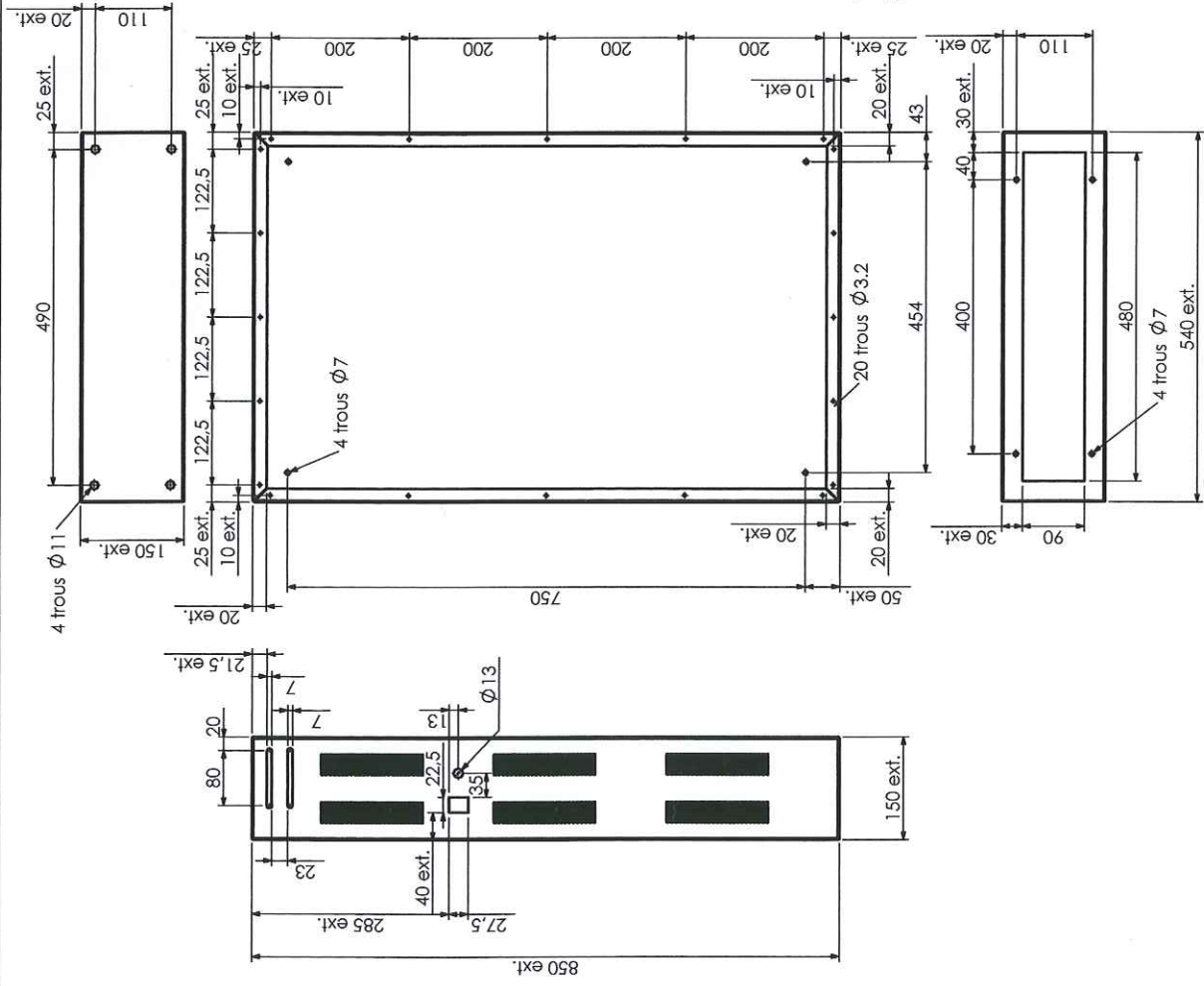


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MECANIQUE		COTES EXT : h12		COTES INT : H12 - ENTRAXE : ±0,2		
APPAREIL		Isolateur - Dossier 132		Ce plan est la propriété de NOROIT et ne peut être reproduit ou communiqué sans son autorisation écrite.		
Dessin	PS	Vérif.	Date	10/04/2009	Ech.	1/15°
MATIERE		PMMA transparent ép.: 8mm - PVC blanc ép.: 15mm				
TRAITEMENT		-				
SOUS-ENS.		Enveloppe rigide		Enveloppe 4 gants spéciale		
DESIGNATION		Enveloppe 4 gants spéciale				
IND. MOD.		N° PRODUIT FINI		330370		









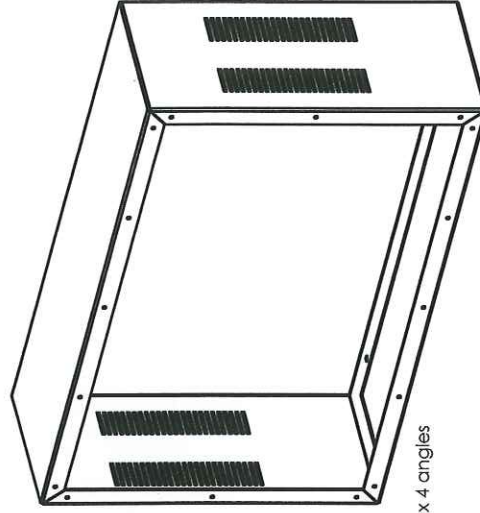
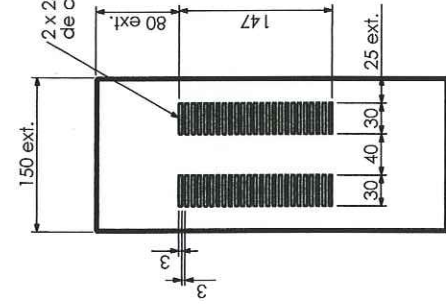
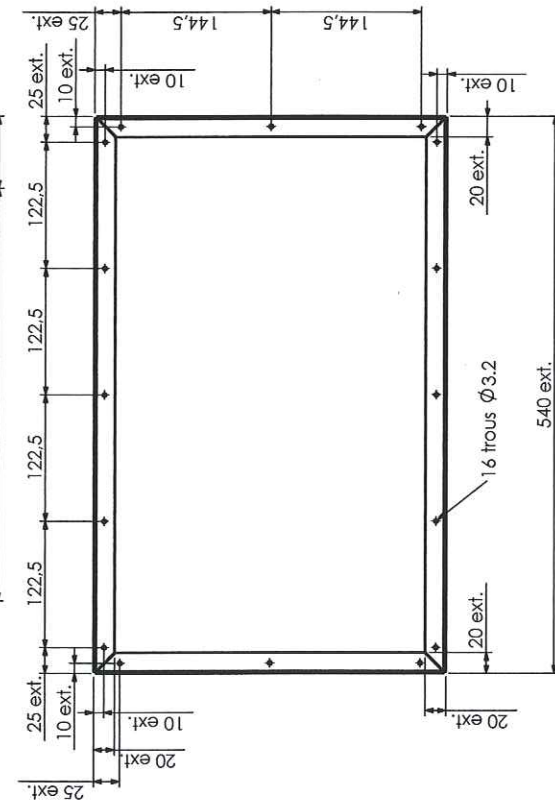
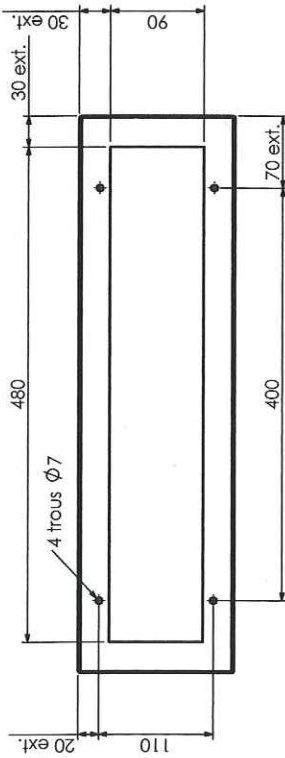
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Indice		Date	Faite par	Modification	
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APPAREIL			MECANIQUE	COTES EXT : H12 - COTES INT : H12 - ENTRAXE : $\pm 0,2$	
Dessin		PS	Vérif.	Date	21/04/2009
Ech.		1/7,5°			
MATERIE		Tôle acier - 15/10°			
TRAITEMENT		Revêtement poudre époxy blanc : RAL 3002			
SOUS-ENS.		Commandes			
DESIGNATION		Caisson inférieur - Armoire de Cdes			
IND. MOD.		N° PRODUIT FINI		330400	
				A	



**Noroit**  
Matériaux de laboratoire

N° PRODUIT FINI  
**330400**

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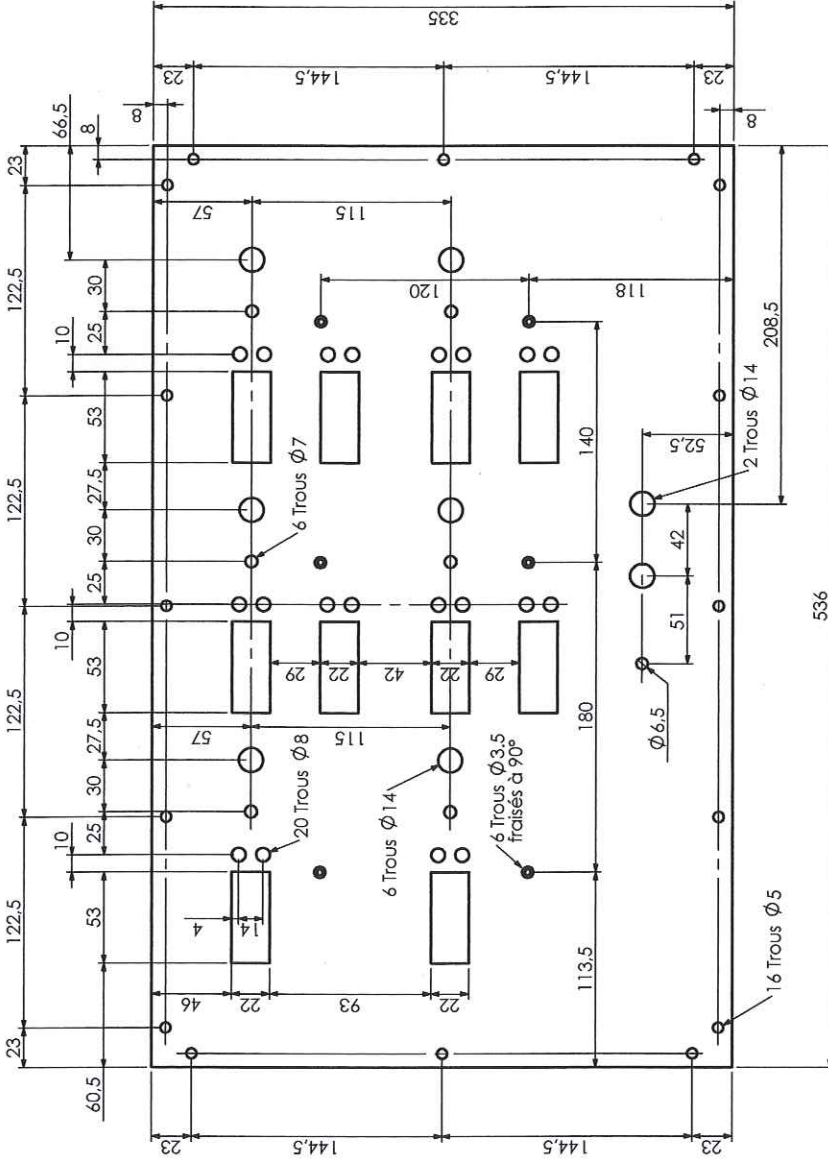
Soudure aux 4 angles



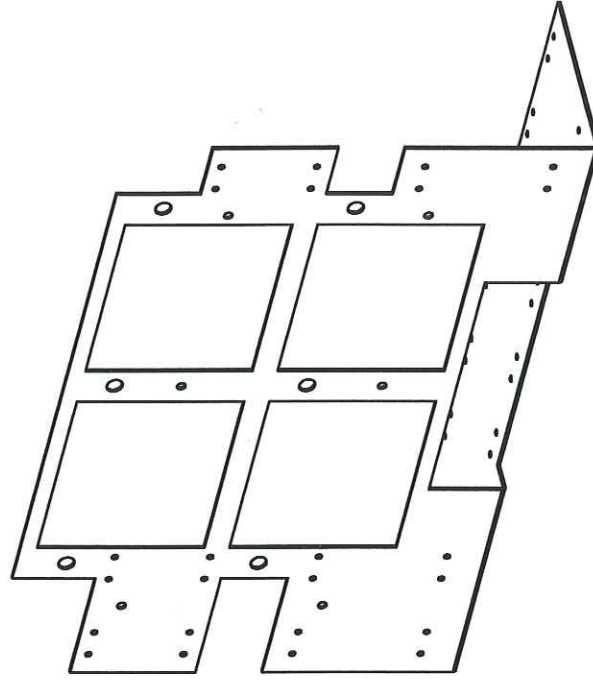
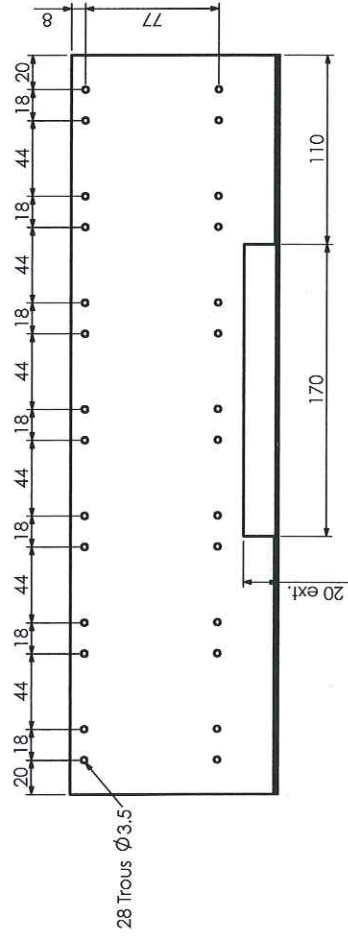
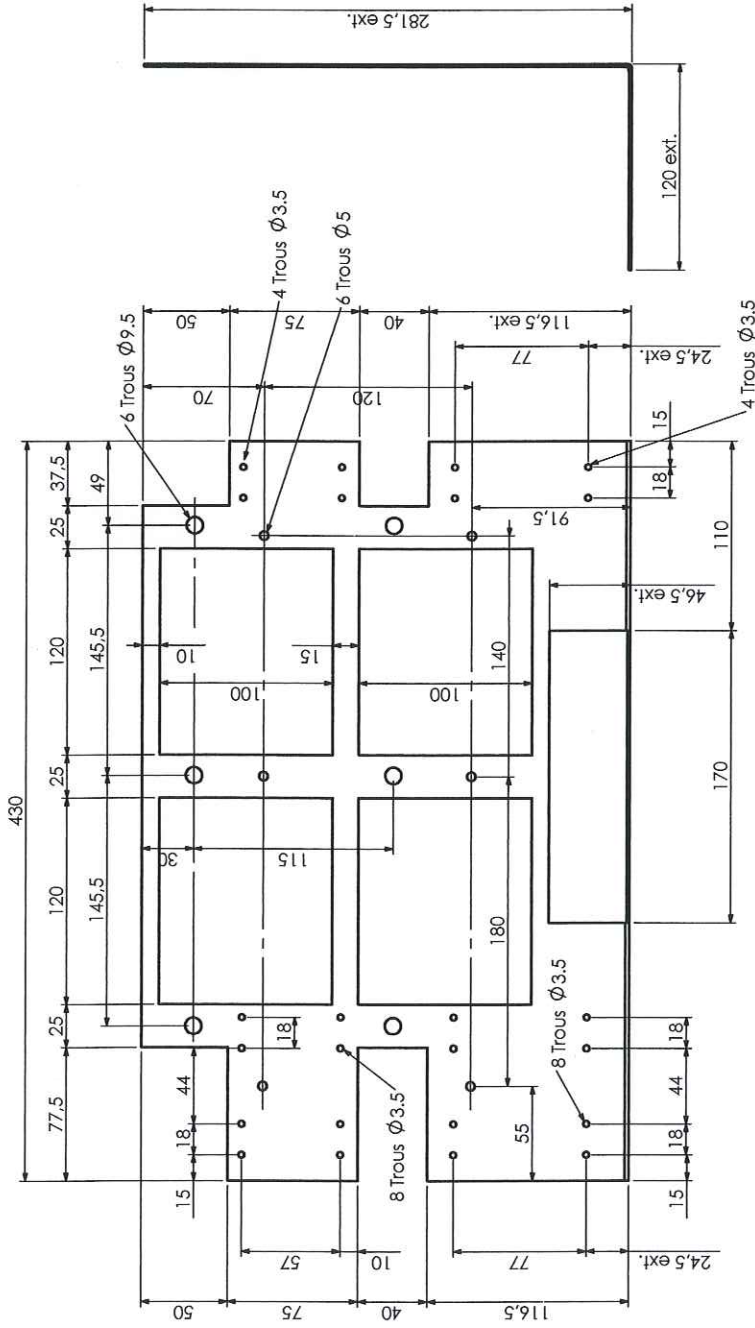
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Modification				
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MECANIQUE				TOLERIE
COTES EXT : ±0,2				TROU : H12 - COTES EXT/INT : ±0,5 - ENTRAXE : ±0,3
COTES INT : H12 - ENTRAXE : ±0,2				

APPAREIL <b>Isolateur N°132</b>		Ce plan est la propriété de NOROIT et ne peut être reproduit ou communiqué sans son autorisation écrite.	
Dessin	PS	Vérfi.	Date
			21/04/2009
Ech. 1/5°			
MATERIE <b>Tôle acier - 15/10°</b>			
TRAITEMENT <b>Revêtement poudre époxy blanc : RAL 9016</b>			
SOUS ENS. <b>Commandes</b>			
DESIGNATION <b>Caisson supérieur - Armoire de Cdes</b>		IND. MOD.	<b>330402</b>





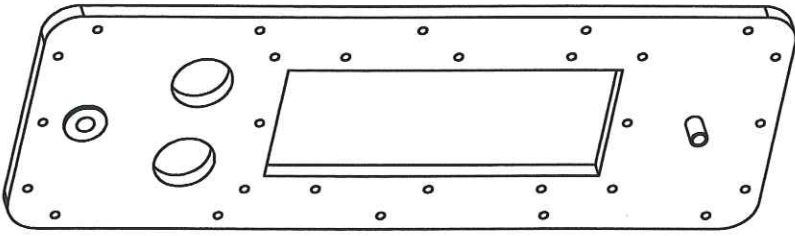
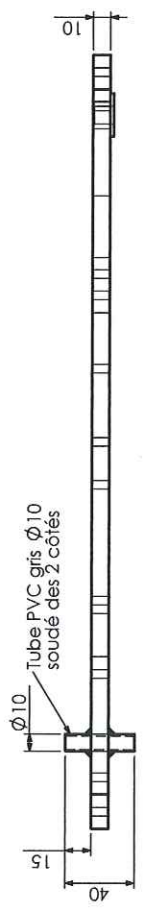
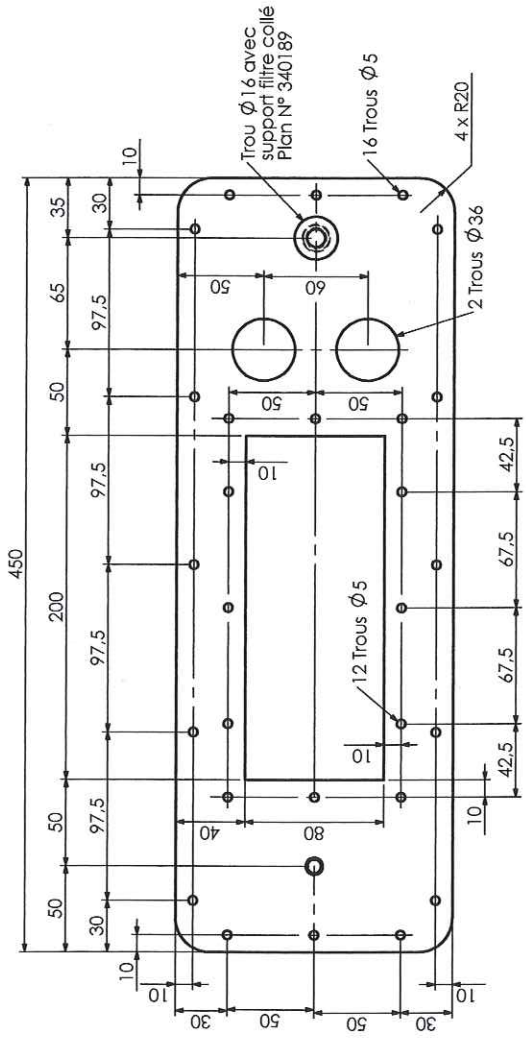
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Index		Date		Faites par		Modification		TOLERANCES GENERALES		TOLERANCE		TOLÉRIE		MECANIQUE		COTES EXT. : ±0,5 - ENTRAXE : ±0,3		COTES INT. : ±0,2 - ENTRAXE : ±0,2		 	
<b>Appareil Isolateur N° 132</b>				Ce plan est la propriété de NOROIT et ne peut être reproduit ou communiqué sans son autorisation écrite.				Dessin PS Vérif. Date 21/04/2009 Echs. 1/3				 Matériaux de laboratoire									
Matière				Tôle acier - 15/10°				TRAITEMENT				Revêtement poudre époxy blanc : RAL 9016									
Sous-ens.				Commandes				N° PRODUIT FINI				IND MOD									
DESIGNATION				Tôle pour commandes				<b>330403</b>				<b>A</b>									



A		21/04/09	PS	Création	
Index		Date	Faite par	Modification	
TOLERANCES GÉNÉRALES		TOLERIE		TROU : H12 - COTES EXT/INT : ±0,5 - ENTRAXE : ±0,3	
APPAREIL		MECANIQUE		COTES EXT : h12 - COTES INT : H12 - ENTRAXE : ±0,2	
Dessin		PS	Vérif.	Date	21/04/2009
Matière		Tôle acier - 15/10°		Ech.	1/3
Traitements		Revêtement poudre époxy blanc : RAL 9016			
Sous-ens.		Commandes			
Designation		Tôle arrière commandes			
				IND MOD	330404 A

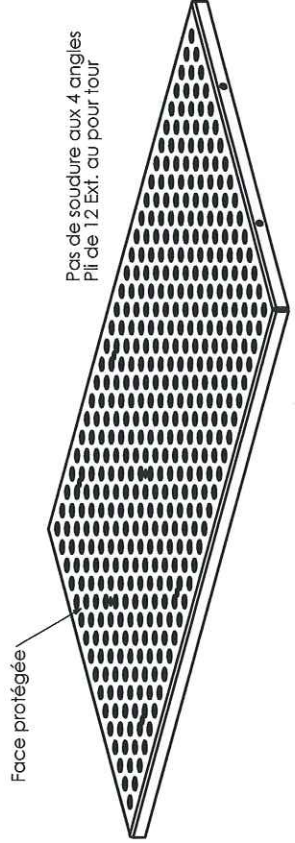
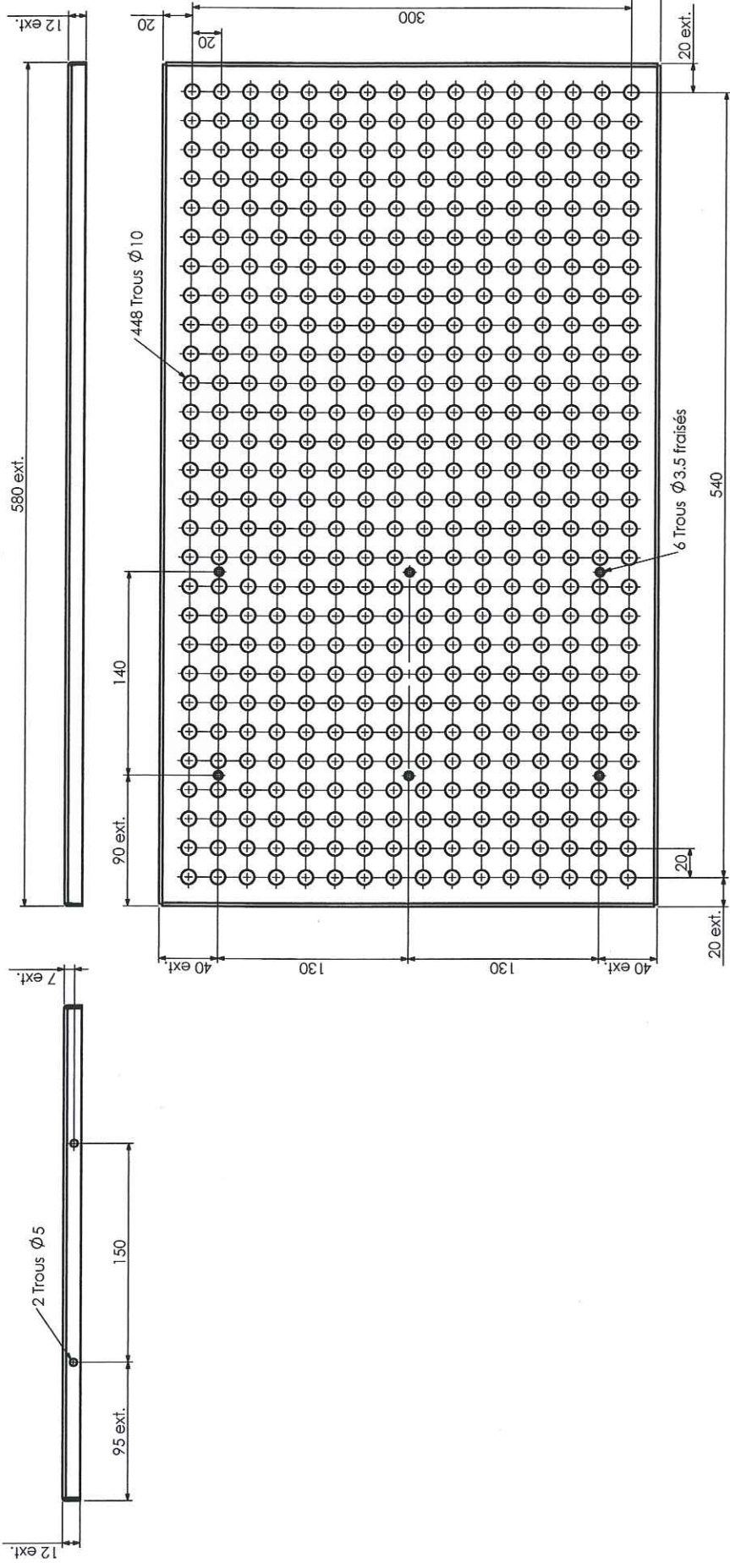
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A		10/04/09	PS	Création		
Index		Date	Faite par	Modification		
TOLERANCES GENERALES		TOLERIE		TROU : H12 - COTES EXT/INT : ±0,5 - ENTRAXE : ±0,3		
APPAREIL		MECANIQUE		COTES EXT : h12 - COTES INT : H12 - ENTRAXE : ±0,2		
Dessin		PS	Vérif.	Date	10/04/2009	Ech. 1/3
MATERIE		PVC blanc ép.: 10mm				
TRAITEMENT						
SOUS ENS.		Platine fluide				
DESIGNATION		Platine fluide - 132				
						IND MOD N° PRODUIT FINI <b>330377</b> <b>A</b>

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Pas de soudure aux 4 angles  
Pli de 12 Ext. au pour tour

A	20/04/09	PS	Création						
Indice	Date	Faité par	Modification						
TOLERANCES GENERALES				TROU : h12 - COTES EXT/INT : $\pm 0,5$ - ENTRAXE : $\pm 0,3$					
				MECANIQUE COTES EXT : h12 - COTES INT : h12 - ENTRAXE : $\pm 0,2$					
APPAREIL				Isolateur					
Dessiné	PS	Vérif.	Date	20/04/2009	Ech.	1/4			
Ce plan est la propriété de NOROIT et ne peut être reproduit ou communiqué sans son autorisation écrite.									
Matière Tôle inox 304L - 15/10° - 1 Face protégée									
TRAITEMENT -									
SOUS ENS. Sas									
								IND. MOD	
								N° PRODUIT FINI	
								330399	
DESIGNATION									
Etagère sas									





## 5. TECHNICAL DOCUMENTATION

- Fans
- Power controller
- Temperature/velocity sensor
- Humidity sensor
- Pressure sensor
- Filter
- Lift table

# AC centrifugal blowers and fans

single inlet, Ø 108 / 120



- **Material:** scroll housing made of die-cast aluminium, impeller made of galvanised sheet steel
- **Type of protection:** IP 44
- **Approvals:** CE

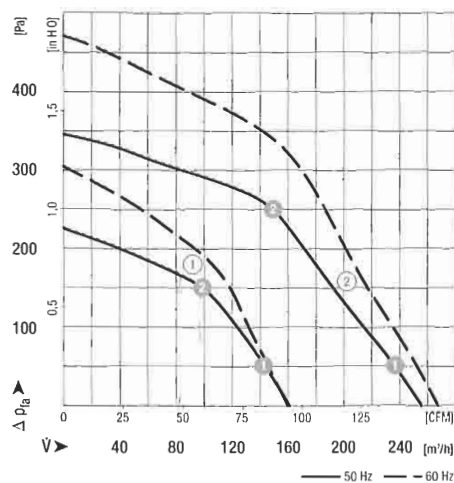
ebm-papst • Mulfingen

Nominal data		Characteristic	Nominal voltage	Frequency	Air flow	Speed/rpm	Power input	Current draw	Capacitor	Sound pressure level	Min. back pressure	Perm. amb. temp.	Mass	Electr. connection
Type	Motor	VAC	Hz	m³/h	min⁻¹	W	A	µF/VDB	dB(A)	Pa	°C	kg		
G2E 108-AG63 -01	M2E 052-BF	①	230	50	160	1850	30	0,14	1,0/400	56	0	-25..+85	1,3	1a)
R2E 108-AG63 -05		②	230	60	160	1850	35	0,16	1,0/400	56	0	-25..+80	0,6	
G2E 120-AR77 -01	M2E 068-BF	①	230	50	255	2350	80	0,35	2,0/450	61	0	-25..+55	1,8	1a)
R2E 120-AR77 -05		②	230	60	265	2450	100	0,44	2,0/450	62	0	-25..+60	1,2	

subject to alterations

	n [min⁻¹]	P <sub>1</sub> [W]
① ①	2070	34
① ②	2470	31
② ①	2460	77
② ②	2665	69

## Characteristics





# PAC2 POWER CONTROLLER

**PAC2**  
X10461

### INTRODUCTION

The PAC module is a high power, full wave AC Phase Angle Controller in a compact package. It is capable of regulating up to 6KW (25A) 230V ac. The PAC2 regulator governs the amount of power supplied to the load, by controlling the phase angle of the AC supply. The low thermal impedance and high electrical isolation provides the equipment designer with a greater flexibility in a wide variety of applications.

### APPLICATIONS

Suitable for most power control applications such as infra/red quartz and ceramic heaters and lighting. It can also be used on inductive loads such as transformers and ac motors.

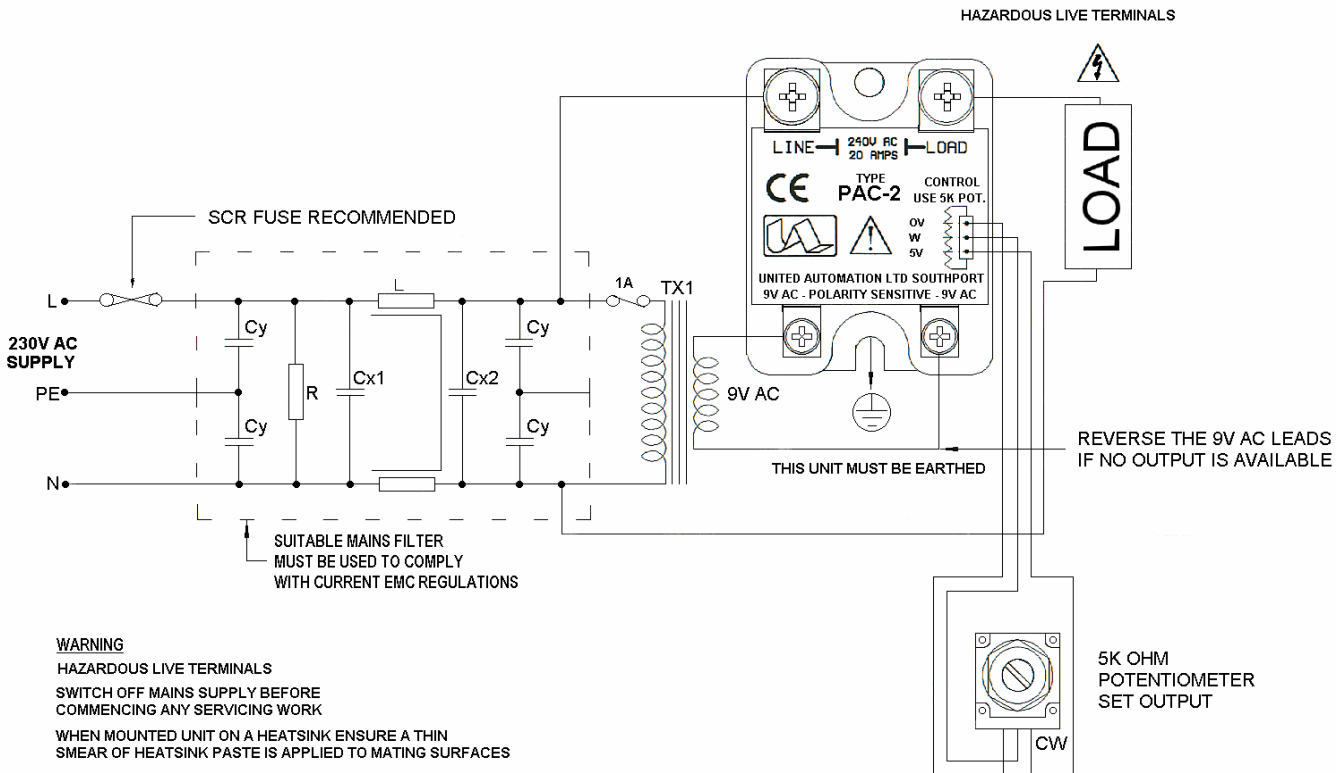
### FEATURES

- Solid state reliability.
- S.M.T
- Simple wiring.
- Rugged and compact
- High current capability.
- Internal snubber.

RoHS Compliant  
Directive  
2002/95/EC

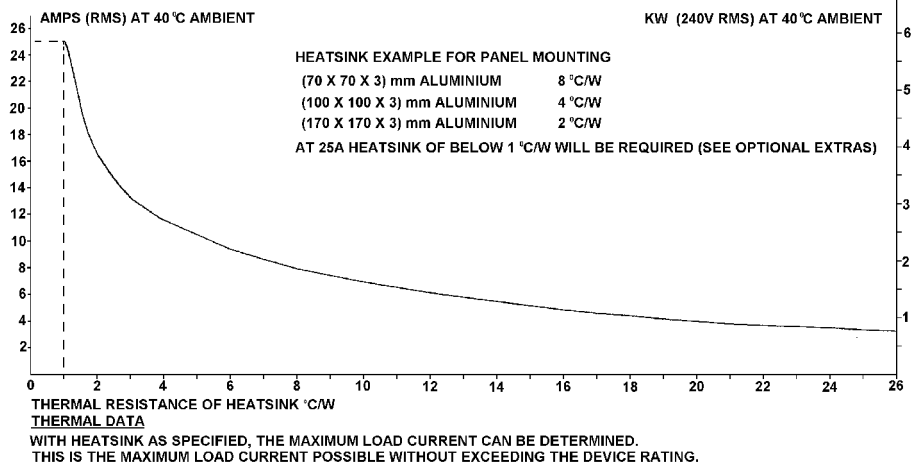


### INSTALLATION



**WARNING**  
HAZARDOUS LIVE TERMINALS  
SWITCH OFF MAINS SUPPLY BEFORE COMMENCING ANY SERVICING WORK  
WHEN MOUNTED UNIT ON A HEATSINK ENSURE A THIN SMEAR OF HEATSINK PASTE IS APPLIED TO MATING SURFACES

## INSTALLATION



## SPECIFICATIONS

AC line voltage	230V +/- 10% @ 50/60 Hz	AC Aux input supply	10V ac @ 50mA
Unit limiting RMS current	25A	I <sup>2</sup> t for fusing	250 A <sup>2</sup> s
Peak one cycle surge (10ms)	250A	Max peak voltage	600Vac
Minimum operating current	0.05A	Leakage current	5mA
Isolation voltage	3500Vrms	Control Signal	0-5v / 5v Aux O/P
Power terminals	M5 x 10mm	Power consumption	1.2 watts
Recommended Potentiometer	5K 1W	Weight	63g
Storage temperature	-20°C to +85°C	Maximum operating temperature	65°C

## FUSING

It is recommended that semiconductor, fast acting type fuses or circuit breakers (Semiconductor - MCB) be used for unit protection and an appropriate safety fuse for unit supply (F1A). On initial operation some loads may need an increased factor of safety (F of S) for unit and/or device protection. See SRA Data/sheet for further information.

## CE MARKING

This product family carries a "CE" marking. These phase angle controllers need a suitable remote filter. For information see recommendation section and contact our sales desk. See Declaration of Conformity.

## RECOMMENDATIONS

Other documents, which may be appropriate for your application, are available on request:

CODE	IDENTITY	DESCRIPTION
X10229	RFI	Filter recommendations: Addressing the EMC Directive
X10213	ITA	Interaction: Uses for phase angle and for burst fire control.
X10255	SRA (LVD)	Safety requirements: Addressing the Low Voltage Directive including, Thermal data/cooling, Live parts warning, Earth requirements and fusing recommendations.
AP02/4	COS	UAL Conditions of sale.

**NOTE:** It is recommended that installation and maintenance of this equipment should be carried out by suitably qualified/trained personnel with reference to the current edition of the I.E.E. wiring regulations (BS7671). The regulations contain important requirements regarding the safety of electrical equipment. For International Standards refer to I.E.C. directive IEC 950.

## ORDER CODE

State part number:

**PAC2**

*Optional extras include: Potentiometer, Filter, Heatsink paste, and Heatsink assembly*



## UNITED AUTOMATION LIMITED

1 Southport Business Park  
Kew  
Southport, PR8 4HQ  
ENGLAND

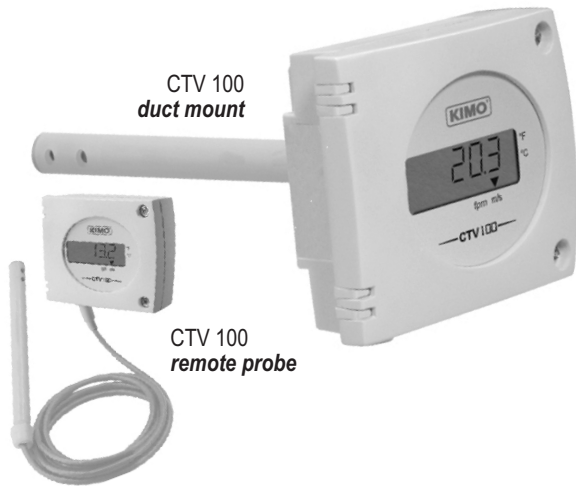
Tel: 0044 (0) 1704 – 516500 Main  
Tel: 0044 (0) 1704 – 516516 Sales  
Fax: 0044 (0) 1704 – 516501  
Enquiry@united-automation.com  
www.united-automation.com  
Date 03/07/01

Page No. 2 of 2 Issue 2



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**Temperature and air velocity transmitter**  
**CTV 100**

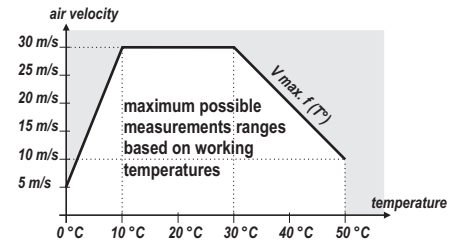


- Temperature and air velocity transmitter type CTV100.
- Ranges from 0-5 m/s to 0-30 m/s and 0 to +50°C, -20 to +80°C, -50 to +50°C, 0 to +100°C (see "Configuration")
- 0-10 V or 4-20 mA output, active, power supply 24 Vac/Vdc (3-4 wires)
- ABS IP 65 housing, with or without display
- Alternating display of air velocity and temperature
- Quick and easy mounting "1/4 turn" system with wall-mount plate

**Features of the transmitter**

**Air velocity**

Working principle : the air velocity measurement is made with a hotwire, in constant thermal equilibrium. The temperature is maintained and measured with a PT 100 element.



Measuring range ..... 0 to 5m/s, 0 to 10m/s, 0 to 15m/s, 0 to 20m/s, 0 to 30m/s

Units of measurement ..... m/s and fpm

Accuracy \* ..... ±3% of reading ±0,3 m/s

Response time ..... 1/e (63%) 2 sec.

Resolution ..... 0,1 m/s

Type of fluid ..... air and neutral gases

**Temperature**

Measuring range ..... 0 to +50°C, -20 to +80°C, -50 to +50°C, 0 to +100°C

Units of measurement ..... °C, °F

Accuracy \* ..... ±0,5% of reading ±0,4°C

Response time ..... 1/e (63%) 5 sec.

Resolution ..... 0,1°C

Type of sensor ..... Pt100 class A as per DIN IEC751

Type of fluid ..... air and neutral gases

**Features of the housing**

WITH or WITHOUT display

Housing ..... ABS

Fire-proof classification ..... HB as per UL94

Dimensions ..... see drawings beside

Protection ..... IP 65

Display ..... 5-digit LCD 5 digits. Dimensions 50x15mm  
..... Alternating display of air velocity and temperature.

Height of the digits ..... 10 mm

Cable grip ..... for cables Ø 7 mm max.

Weight ..... 145 g (with display) - 110 g (without display)



**Technical Specifications**

Output/ Power supply ..... active 0-10 V or 4-20 mA (power supply 24 Vac/Vdc±10%), 3-4 wires  
..... maximum load : 500 Ohms (4-20 mA)  
..... minimum load : 1 K Ohms (0-10 V)

Consumption ..... 40 mA (0-10V) or max. 80 mA (4-20 mA)

Electro-magnetical compatibility ..... EN 61326

Electrical connection ..... screw terminal block for cable Ø1.5mm² max.

Communication to PC ..... Kimo RS 232 cable

Working temperature (housing) ..... 0 to +50°C

Working temperature (probe) ..... 0 to +50°C

Storage temperature ..... -10 to +70°C

Environment ..... air and neutral gases

\*All the accuracies indicated in this technical datasheet were stated in laboratories conditions, and can be guaranteed for measurements carried out in the same conditions, or carried out with calibration compensation.

**Part number**

To order, just add the codes to complete the part number :

**Transmitter / power supply / Output**

**A** Active • 24 Vac/Vdc • 4-20mA  
**V** Active • 24 Vac/Vdc • 0-10V

**Display**

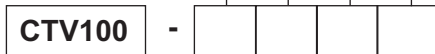
**O** With display  
**N** Without display

**Probe**

**A** Duct mount  
**D** Remote

**Length**

**150** 150 mm  
**300** 300 mm



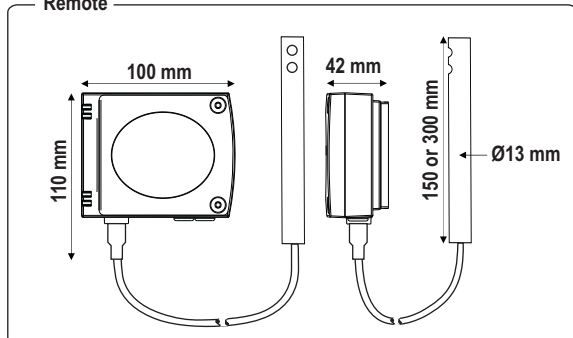
Example : CTV100-AOD150

Model : air velocity transmitter CTV100, active transmitter 4-20 mA output, with display and remote probe length 150mm

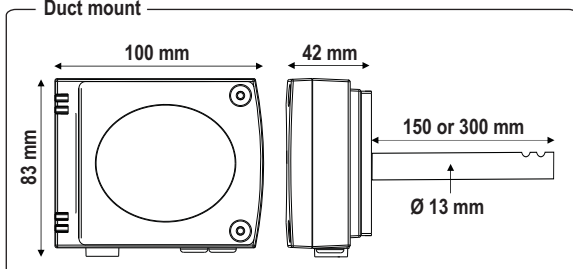
**Dimensions of the housing**

(including the wall-mount plate)

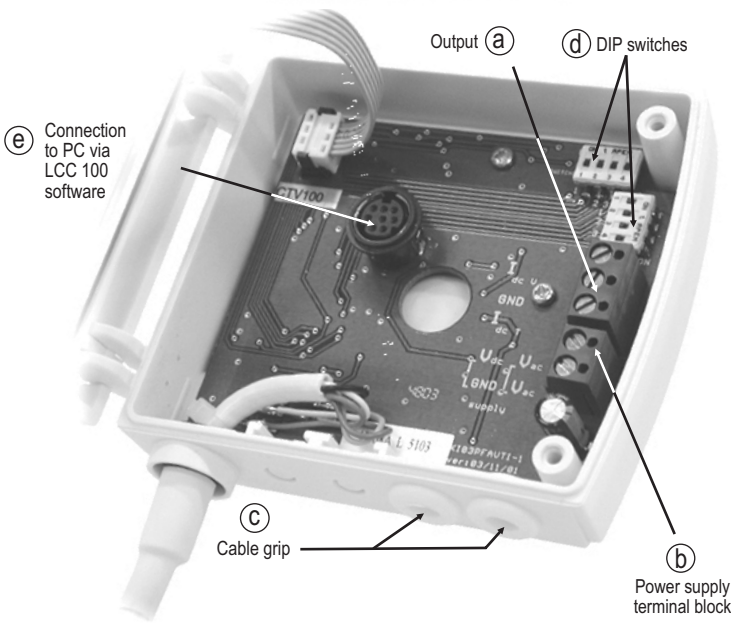
Remote



Duct mount



## Connection



For the models

### CTV 100-ANA, CTV 100-AND, CTV 100-AOA, CTV100-AOD

#### • Output 4-20 mA - active

- (a)  $\text{Idc V}$  .....direct current (air velocity)
- $\text{GND}$  .....ground
- $\text{Idc T}$  .....direct current (temperature)

**or**

For the models

### CTV 100-VNA, CTV 100-VND, CTV 100-VOA, CTV100-VOD

#### • Output 0-10 V - active

- (a)  $\text{Vdc V}$  .....direct voltage (air velocity)
- $\text{GND}$  .....ground
- $\text{Vdc T}$  .....direct voltage (temperature)

#### Power supply

- (b)  $\text{Vdc}$  .....direct voltage
  - $\text{GND}$  .....ground
- or**
- (b)  $\text{Vac}$  .....alternative voltage (phase)
  - $\text{Vac}$  .....alternative voltage (neutral)

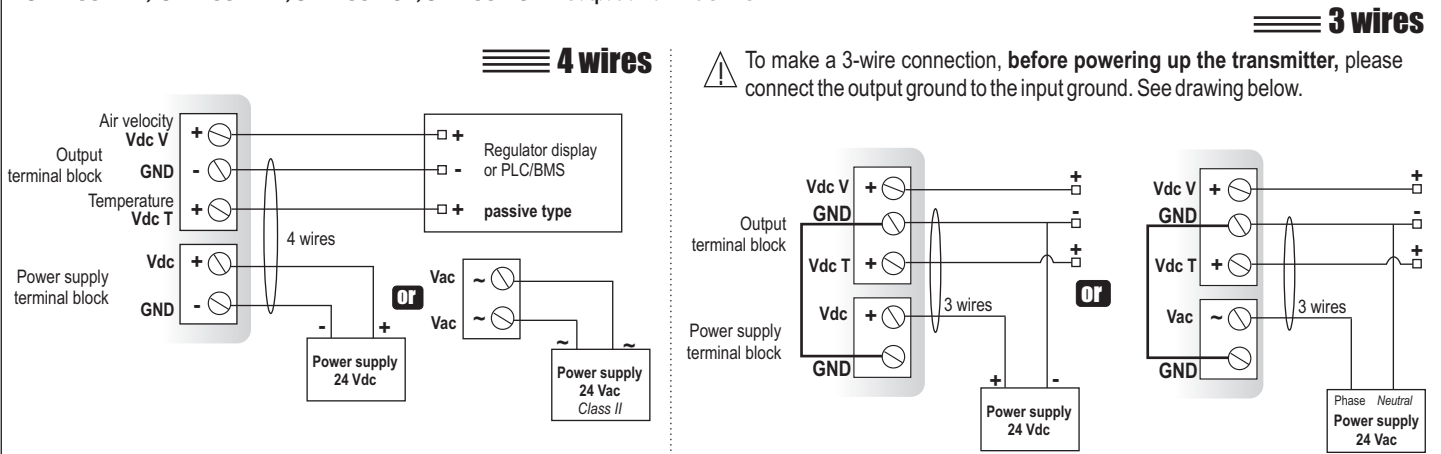
(c) Cable grip : to insert the cable, it is required to slightly cut the rubber.

## Electrical connection - as per norm NFC15-100

⚠ This connection must be made by a qualified technician. To make the connection, the transmitter must not be energized.

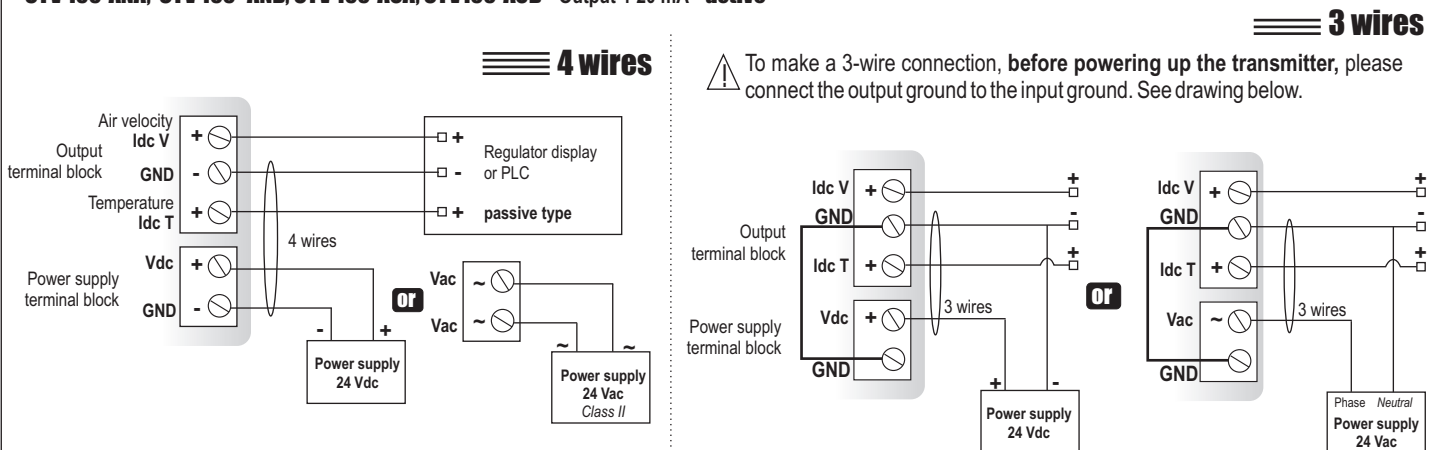
For the models

### CTV 100-VNA, CTV 100-VND, CTV 100-VOA, CTV100-VOD • Output 0-10 V - active



For the models

### CTV 100-ANA, CTV 100-AND, CTV 100-AOA, CTV100-AOD • Output 4-20 mA - active



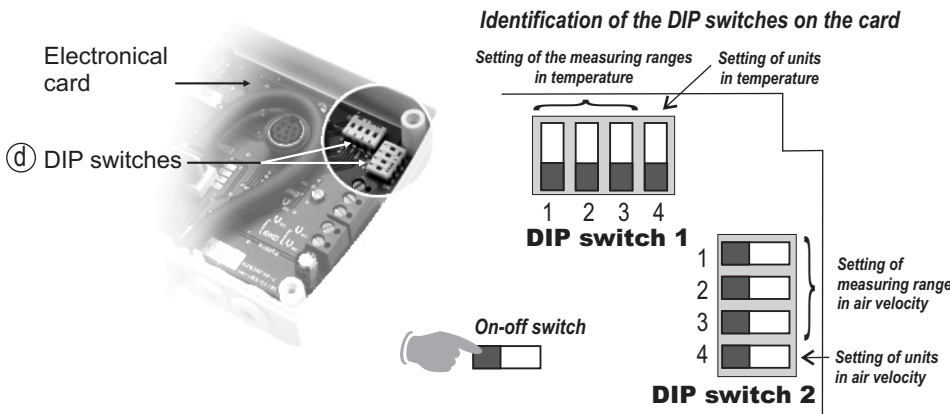


## Configuration

It is possible to configure the measuring ranges, the units, the output of the transmitter (according to the model) either by **DIP switch** and/or via **software** (connections ③ and ④ on drawing "connection").

### Configuration by DIP switch

To configure the transmitter, please unscrew the 2 screws from the housing and then, open it.



To configure the transmitter, **it must not be energized**. Then, you can make the settings required, thanks to the DIP switches (as shown on the drawing beside). When the transmitter is configured, you can power it up.

**Caution !**

Please follow carefully the combinations beside with the DIP switch. If the combinations are wrong, the following message will appear on the display of the transmitter "CONF ERROR". In that case, you will have to unplug the transmitter, replace the DIP switches correctly, and then power the transmitter up.

#### Temperature units setting DIP switch 1

To set the measuring unit, please put the on-off switch 4 of units as shown beside.

Configurations	°C	°F
Combinations	 1 2 3 4	 1 2 3 4

#### Temperature measuring ranges setting DIP switch 1

To set the measuring range in temperature, please put the on-off switches 1, 2 and 3 of ranges as shown beside.

Configurations	0 to 50°C	-20 to 80°C	-50 to 50°C	0 to 100°C
Combinations	 1 2 3 4	 1 2 3 4	 1 2 3 4	 1 2 3 4

#### Air velocity measuring units setting DIP switch 2

To set the measuring unit in air velocity, please put the on-off switch 4 of units as shown beside.

Configurations	m/s	fpm
Combinations	 1 2 3 4	 1 2 3 4

#### Air velocity measuring ranges setting DIP switch 2

To set the measuring range in air velocity, please put the on-off switches 1, 2 and 3 of the measuring range as shown beside.

Configurations	0 to 5 m/s	0 to 10 m/s	0 to 15 m/s	0 to 20 m/s	0 to 30 m/s
Combinations	 1 2 3 4	 1 2 3 4	 1 2 3 4	 1 2 3 4	 1 2 3 4

### Initialization the transmitter

When the transmitter is powered up, it initializes and displays the digits  $\overline{00000}$ , and then its configuration including :

- the measuring range
- the analog output.

#### 1- The measuring range

The following message is displayed :  $\overline{Lo}$ . This is the low value of the measuring range, and its digit value : **ex** :  $\overline{0}$ .  
 The following message is displayed :  $\overline{Hi}$ . This is the high value of the measuring range and its digit value : **ex** :  $\overline{30}$ .  
 The arrow displayed (at the bottom or on the right of the screen) is relative to the unit of measurement : **ex** : from 0 to 30 m/s.

#### 2- The analog output

If the analog output is in 4-20mA, then the following message will appear  $\overline{4-20A}$ .  
 If the analog output is 0-10 V, then the following message will appear  $\overline{0-10V}$ .

The transmitter can measure several parameters (CTV 100 => air velocity + temperature). The transmitter will first display the configuration of air velocity parameters, and secondly the configuration of temperature parameters.

After the display of the configurations, the transmitter displays  $\overline{- - - -}$ , which confirms that the initialization is finished and you can start the measurements.



■ **Configuration via software** (with optional LCC100 software)

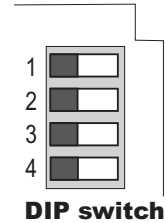


**An easy and friendly configuration with the software !**

You can configure your own intermediary ranges.

Example : for a transmitter with a range of 0-30 m/s, the minimum delta of the range is 5 m/s. It means that you can configure your transmitter from 5 to 10 m/s.

• To access the configuration via software, you must first position **the DIP switches** as per the following picture (shown beside), and then connect the cable to the connection of the transmitter (see connection drawing).



• Please refer to the user manual of the LCC 100 to make the configuration.

**Caution !**

The configuration of the parameters can be done **either by DIP switch, or by software** (you cannot combine both solutions).



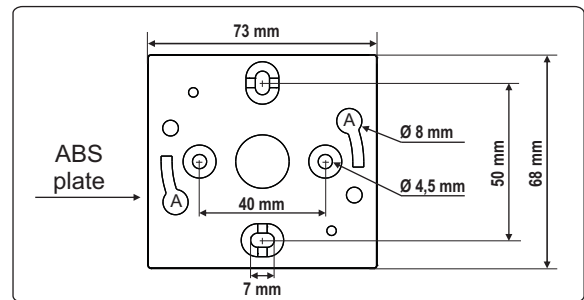
■ **Mounting**

**Wall-mount**

Installation : mount the ABS plate on the wall (this plate is supplied with the transmitter). Drilling : Ø 6 mm (with the screws and pins supplied with the transmitter).

Insert the transmitter on the plate (see A on the drawing beside) and rotate its housing in clockwise direction until you hear a "click" which confirms that the transmitter is correctly installed).

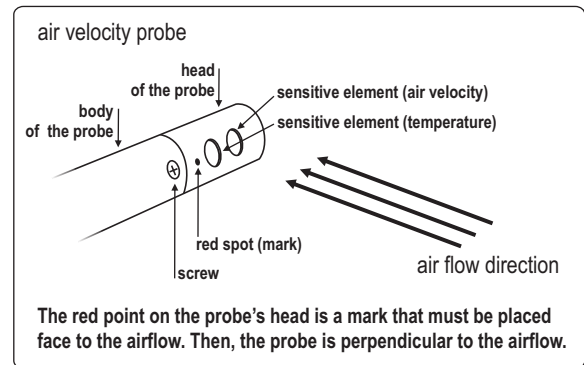
For the model with duct mount, an additional drilling of Ø 14 mm must be done before mounting the plate.



**Position of the measuring element in the air flow**

The probe must be placed perpendicular to the air flow, as shown beside. For the duct mount probes, you can place the probe's head front to the air flow, and keep the housing straight :

- Locate the red point marked on the probe's head.
- Remove the screw located on the tip of the probe's body.
- Rotate the probe's head by ¼ turn, ½ turn or ¾ turn, in order to place the red spot front to the air flow.
- replace the screw on the probe's body.



■ **Maintenance**

Please avoid any aggressive solvent.

Please protect the transmitter and its probes from any cleaning product containing formol, that may be used for cleaning rooms or ducts.

Please clean the sensitive element with the special cleaning spray sold by Kimo.

■ **Options**

- Power supply class 2, input 230 Vac, output 24 Vdc, ref.KIAL-100A
- Configuration software LCC 100 with RS 232 cable.



■ **Accessories**

- Sliding fittings
- Mounting brackets
- Wall-mount support for hotwire probe



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Distributed by :

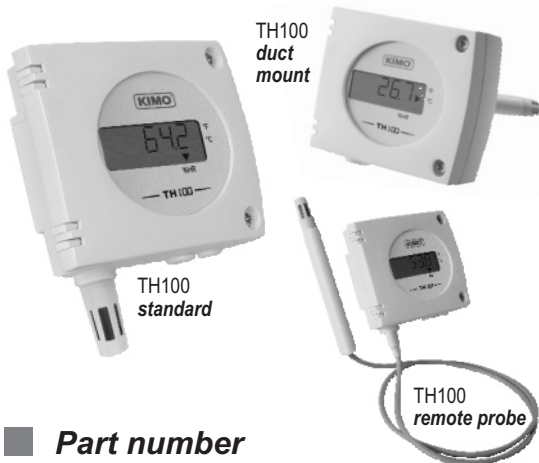
**EXPORT DEPARTMENT**

Tel : + 33. 1. 60. 06. 69. 25 - Fax : + 33. 1. 60. 06. 69. 29  
e-mail : [export@kimo.fr](mailto:export@kimo.fr)



Ref. FT ang - CTV 100 - 06/05 B - We reserve the right to modify the characteristics of our products without notice.

**Temperature and humidity transmitter  
TH 100**



- Humidity and temperature transmitter type TH100.
- Measuring ranges 0-100%RH and -50 to +50°C, -20 to +80°C, 0 to +50°C, 0 to +100°C (see "Configuration")
- 0-10 V output, active sensor, power supply 24 Vac/Vdc (3-4wires) or 4-20 mA output, passive loop, power supply 18 to 30 Vdc (2 wires).
- Housing ABS IP65 with or without display.
- Alternating display of humidity and temperature
- Quick and easy mounting "1/4 turn" system on wall-mount plate.

**Part number**

To order, just add the codes to complete the part number :

**Transmitter / Power supply / Output**

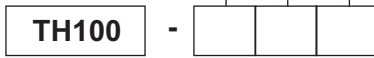
**V** Active • 24 Vac/Vdc • 0-10V  
**A** Passive • 18/30 Vdc • 4-20 mA

**Display**

**O** With display  
**N** Without display

**Probe**

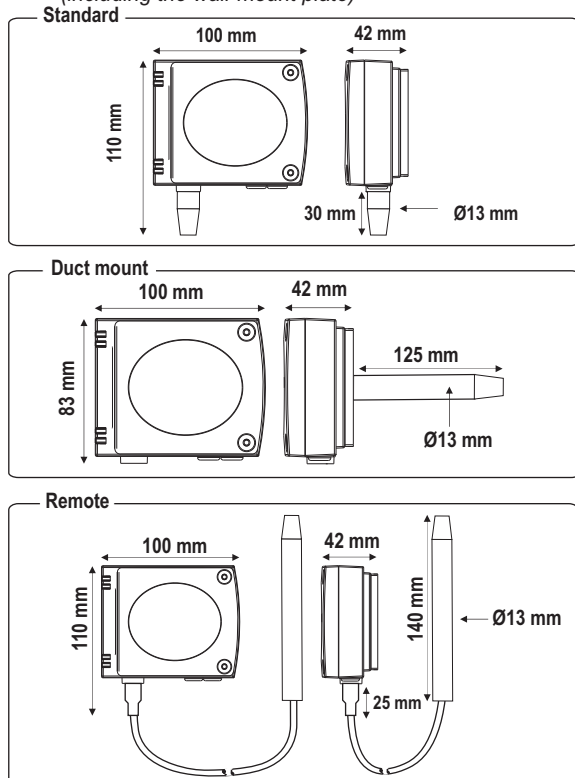
**S** Standard  
**A** Duct mount  
**D** Remote



**Example : TH100-VOD**  
Model : temperature and humidity transmitter TH 100, active sensor, 0-10 V output, with display and remote probe.

**Dimensions of the housing**

(including the wall-mount plate)



**Features of the transmitter**

**Humidity**

Working principle : the measurement of temperature and humidity is made by only one digital component CMOS (complementary metal-oxide semiconductor), including a capacitive element and a thermistor. This technology guarantees an excellent stability in the long term, along with a great accuracy of the measurement.

- Measuring range.....0 to 100 % RH
- Unit of measurement.....% RH
- Response time.....1/e (63%) 4 s
- Resolution.....0,1% RH
- Type of fluid.....air and neutral gases

**HYGROMETRY PROBE :**

Guaranteed Accuracy Limits\* (GAL) = ±2,95 % RH between 18 and 28°C (normal measurement range)  
Measuring range : 0 to 100%RH  
Short-term drift : 1% RH / year

\* GAL= Et + Ehl + k (uet<sup>2</sup>+ur<sup>2</sup>+ud<sup>2</sup>+us<sup>2</sup>)/2

As per the Charter 2000/2001 Hygrometers with :  
uet : uncertainty of calibration = ± 0,55% RH  
ur : uncertainty of resolution = ± 0,003% RH  
ud : manufacturing dispersion = ± 0,2% RH  
us : comparison repeatability = 0,13% RH  
Et : temperature coefficient error = ± 0,42%RH  
Ehl : linearity and hysteresis errors = ± 1,33% RH  
k : coverage factor value = 2

\*As per norm NFX 15-113 and the Charter "2000-2001 HYGROMETERS.

**Temperature**

- Measuring range.....0 to +50°C, -20 to +80°C, -50 to +50°C, 0 to +100°C
- Unit of measurement.....°C, °F
- Accuracy \*.....±1% of reading ±0,4°C in the range 5 to 80°C  
±2% of reading ±0,6°C in the range -20 to 5°C
- Response time.....1/e (63%) 15 s
- Resolution.....0,1°C
- Type of fluid.....air and neutral gases

\*All the accuracies indicated in this technical datasheet were stated in laboratories conditions, and can be guaranteed for measurements carried out in the same conditions, or carried out with calibration compensation.

**Features of the housing**

WITH or WITHOUT display



- Housing.....ABS
- Fire-proof classification.....HB as per UL94
- Dimensions.....see drawing beside
- Protection.....IP65
- Display.....5-digit LCD. Dimensions 50 x 15 mm  
Alternating display of humidity and temperature.
- Height of the digits.....10 mm
- Cable grip.....for cable Ø 7 mm maxi.
- Weight.....145 g (with display) - 110g (without display)

## Technical Specifications

**Output / Power supply** .....active 0-10 V (power supply 24 Vac/Vdc  $\pm 10\%$ ), 3-4 wires  
 passive loop 4-20 mA (power supply 18/30 Vdc), 2 wires  
 maximum load : 500 Ohms (4-20 mA)  
 minimum load : 1 K Ohms (0-10 V)

**Consumption** .....2 VA (0-10V) or max. 22 mA (4-20 mA)

**Electro-magnetical compatibility** ...EN 61326

**Electrical connection** .....screw terminal block for cable  $\varnothing$  1.5 mm<sup>2</sup>  
 max.

**Communication to PC** ..... Kimo RS 232 cable

**Working temperature(housing)** ....0 to +50°C

**Working temperature (probe)** .....0 to +50°C (standard)  
 -20 to +80°C (remote and duct mount)

**Storage temperature** .....-10 to +70°C

**Environment** .....air and neutral gases

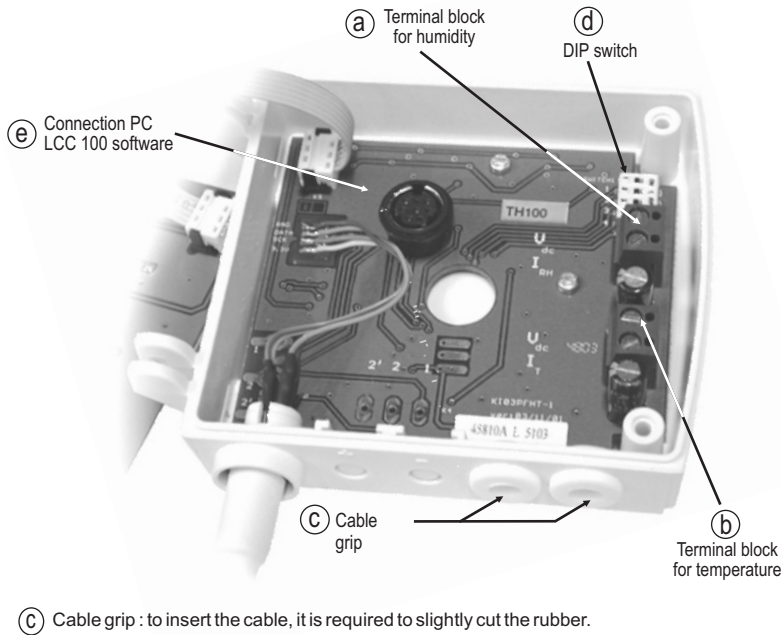
**Warm up time** .....30 minutes

## Connection



For the models

**TH 100 - AOS, TH100 - ANS, TH 100 - AOD, TH 100 - AND, TH 100 - AOA, TH 100 - ANA** • Output 4-20 mA - **passive loop**

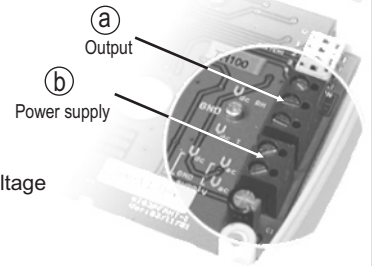


- (a)  $\begin{matrix} \text{Vdc} & \dots\dots & \text{direct voltage} \\ \text{IRH} & \dots\dots & \text{direct current (humidity)} \end{matrix}$
- (b)  $\begin{matrix} \text{Vdc} & \dots\dots & \text{direct voltage} \\ \text{IT} & \dots\dots & \text{direct current (temperature)} \end{matrix}$

For the models

**TH 100 - VOS, TH100 - VNS, TH 100 - VOD, TH 100 - VND, TH 100 - VOA, TH 100 - VNA** • Output 0-10 V - **active**

- (a)  $\begin{matrix} \text{Vdc RH} & \dots\dots & \text{direct voltage (humidity)} \\ \text{GND} & \dots\dots & \text{ground} \\ \text{Vdc T} & \dots\dots & \text{direct voltage (temperature)} \end{matrix}$



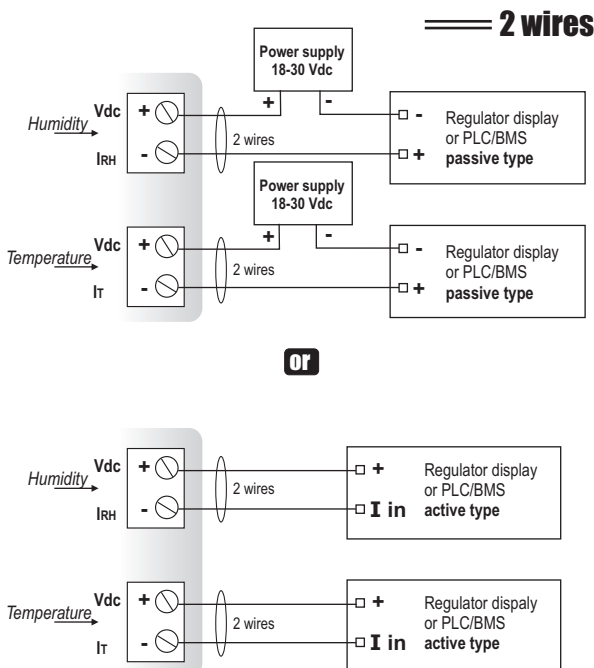
- Power supply**
- (b)  $\begin{matrix} \text{Vdc} & \dots\dots & \text{direct voltage} \\ \text{GND} & \dots\dots & \text{ground} \end{matrix}$
- OR**
- (b)  $\begin{matrix} \text{Vac} & \dots\dots & \text{alternative voltage (phase)} \\ \text{Vac} & \dots\dots & \text{alternative voltage (neutral)} \end{matrix}$

## Electrical connection - as per norm NFC15-100

This connection must be made by a qualified technician. To make the connection, the transmitter must not be energized.

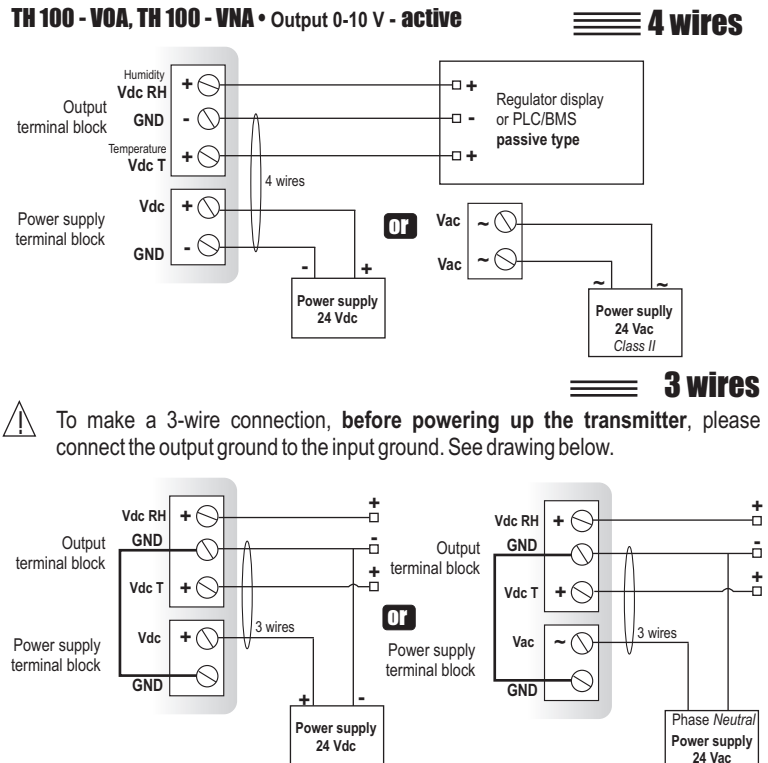
For the models

**TH 100 - AOS, TH100 - ANS, TH 100 - AOD, TH 100 - AND, TH 100 - AOA, TH 100 - ANA** • Output 4-20 mA - **passive**



For the models

**TH 100 - VOS, TH100 - VNS, TH 100 - VOD, TH 100 - VND, TH 100 - VOA, TH 100 - VNA** • Output 0-10 V - **active**

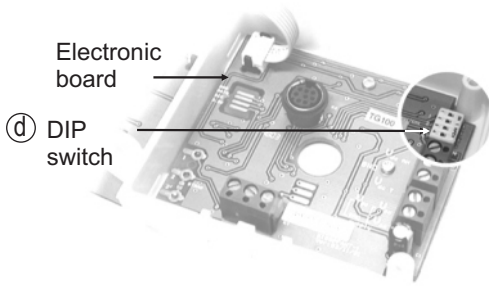


## Configuration

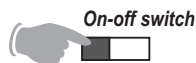
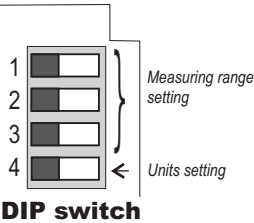
It is possible to configure the measuring ranges, the units, the output of the transmitter (according to the model) either by **DIP switch** and/or via **software** (connections ⑥ and ⑦ on drawing "connection").

### Configuration by DIP switch

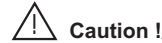
To configure the instrument, please unscrew the 2 screws from the housing, and then open it .



Identification of the DIP switches on the electronic card



To configure the transmitter, **it must not be energized**. Then, you can make the settings required, with the DIP switches (as shown on the drawing beside). When the transmitter is configured, you can power it up.



**Caution !**

Please follow carefully the combinations beside with the DIP switch.

If the combination are wrongly done, the following message will appear on the display of the transmitter "CONF ERROR". In that case, you will have to unplug the transmitter, replace the DIP switches correctly, and then power the transmitter up.

### Units setting

To set the measuring unit, put the on-off switch 4 of units as shown beside.

Configurations	°C	°F
Combinations	1	1
	2	2
	3	3
	4	4

### Measuring range setting

To set the measuring range, put the on-off switches 1, 2 and 3 of the measuring range as shown beside.

Configurations	0 to 50 °C	-20 to 80 °C	-50 to 50 °C	0 to 100 °C
Combinations	1	1	1	1
	2	2	2	2
	3	3	3	3
	4	4	4	4

### Initialization the transmitter

When the transmitter is powered up, it initializes and displays the digits  $\boxed{0.0000}$ , and then its configuration including :  
 - the measuring range  
 - the analog output.

#### 1- The measuring range

The following message is displayed :  $\boxed{Lo}$ . This is the low value of the measuring range, and its digit value : **ex** :  $\boxed{0}$ .  
 The following message is displayed :  $\boxed{Hi}$ . This is the high value of the measuring range and its digit value : **ex** :  $\boxed{100}$ .  
 The arrow displayed (at the bottom or on the right of the screen) is relative to the unit of measurement : **ex** : from 0 to 100 %RH.

#### 2 - The analog output

If the analog output is in 4-20mA, then the following message will appear  $\boxed{4-20A}$ .  
 If the analog output is 0-10 V, then the following message will appear  $\boxed{0-10V}$ .

The transmitter can measure several parameters (TH 100 => humidity + temperature). The transmitter will first display the configuration of humidity parameters, and secondly the configuration of temperature parameters.

After the display of the configurations, the transmitter displays  $\boxed{- - - -}$ , which confirms that the initialization is finished and you can start the measurements.

## ■ Configuration by **software** (LCC100 coming in option)



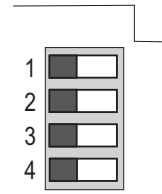
### An easy and friendly configuration with the software !

You can configure your own intermediary ranges, the offset...

Example :

- For a transmitter from 0-100°C, the minimum delta of the range is 20°C. You can also configure your transmitter from 0 to +70°C, or from -10 to +10°C...
- In order to avoid any eventual drift of the transmitter, you can add an offset to the value displayed by the TH 100. For example : the TH100 displays 48%RH, a standard instrument displays 45%RH. Then, you can integrate an offset of -3 to the value displayed by the TH 100, thanks to the LCC100 software.

To have access to the configuration with software, **first of all**, it is required to **set the DIP switch as shown below**, then to connect the cable to the transmitter (see beside and see "Connection"). **To make the configuration, please refer to the user manual of the LCC 100.**



**DIP switch**



### ⚠ Caution !

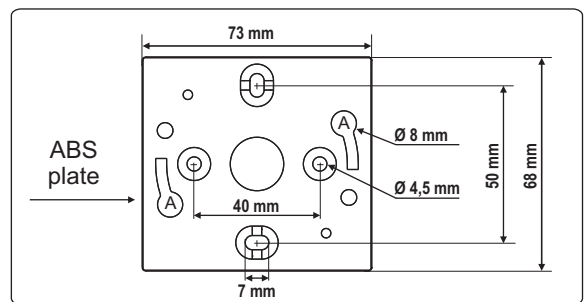
The configuration of the parameters can be done **either by DIP switch, OR by software** (you cannot combine both solutions).

## ■ Mounting

To make the wall-mounting, install the ABS plate onto the wall (this plate is supplied with the transmitter). Drilling : Ø 6 mm (with the screws and pins supplied with the transmitter).

Insert the transmitter on the plate (see A on the drawing beside) and make its housing rotated in clockwise direction till you hear a "click", which confirms that the transmitter is correctly installed).

For the model with duct want an additional drilling of Ø 14 mm must be done.



## ■ Maintenance

Please avoid any aggressive solvent.

Please protect the transmitter and its probes from any cleaning product containing formol, that may be used for cleaning rooms or ducts.

## ■ Options

- Power supply class 2, input 230 Vac, output 24 Vac, ref.KIAL-100A
- Configuration software LCC 100 with cable RS 232



## ■ Accessories

- Stainless steel connection
- PC connection gland
- ABS connection with connection gland
- Stainless steel connections
- Wall-mount plate for humidity remote probe

[www.kimo.fr](http://www.kimo.fr)

Distributed by :



EXPORT DEPARTMENT

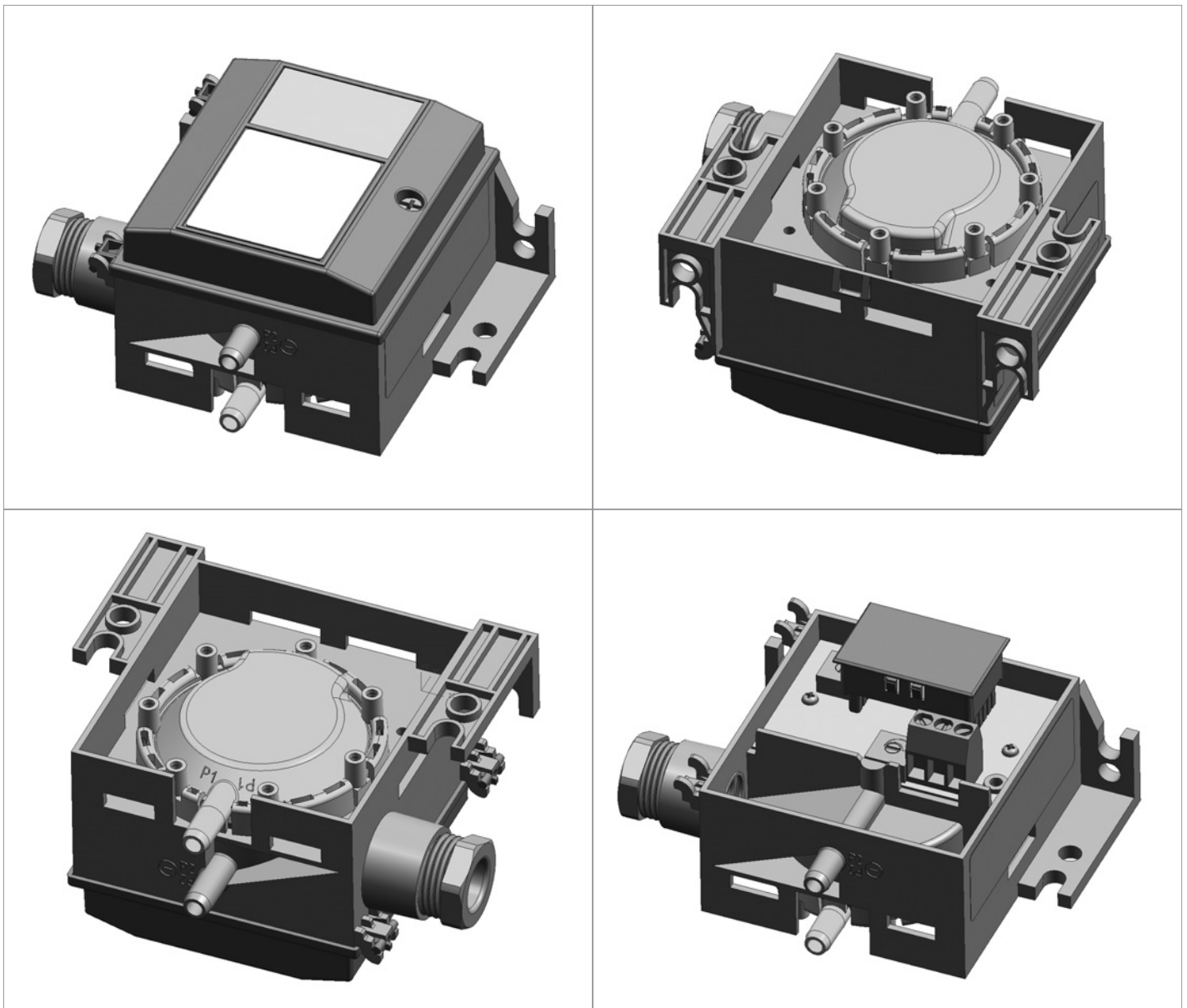
Tel : + 33. 1. 60. 06. 69. 25 - Fax : + 33. 1. 60. 06. 69. 29

e-mail : [export@kimo.fr](mailto:export@kimo.fr)



## Relative and differential pressure transmitter

-0.5 ... +0.5 mbar / 0 ... 1 – 50 mbar



**Huba Control**

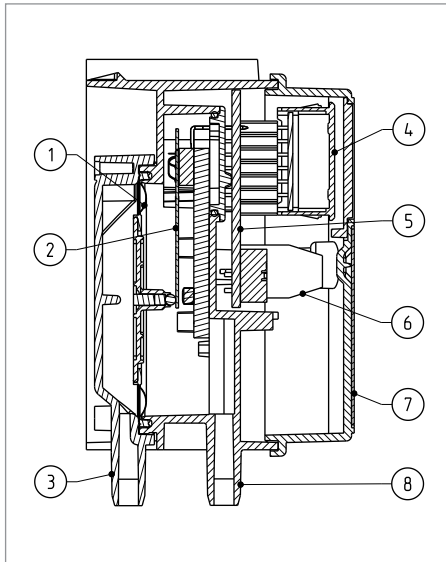
FEINE MESSIDEEN FÜR DRUCK UND STRÖMUNG  
FOR FINE PRESSURE AND FLOW MEASUREMENT  
LA FINESSE DES MESURES DE PRESSION ET DE DEBIT

## Technical overview

The differential pressure transmitters of the Type 694 series incorporate a proven ceramic fulcrum lever technology.

They deliver adjusted and temperature-compensated sensor signals, available as standard voltage or current outputs.

They are ideal for registering low air flow in air conditioning systems and for the measurement of fine pressures in laboratory, environmental and clean-room applications.



## Legend to cross-section drawing

- 1 Diaphragm
- 2 Sensor element
- 3 P1 Pressure connection (higher pressure)
- 4 Display (option)
- 5 Amplified electronics
- 6 Connection terminals
- 7 Cover
- 8 P2 Pressure connection (lower pressure)

## The distinct advantages

- Compact construction
- Fast, easy mounting.  
Housing incorporates integral bracket for wall or ceiling mounting. Snap-on cover with a single screw
- Available with or without LCD display
- Available with or without root-extracted output
- Available zero point and full scale adjustable
- Attractive price/performance ratio

## Medium

Air and neutral gases

## Pressure range

–0.5 ... +0.5 mbar / 0 ... 1 – 50 mbar  
 –50 ... +50 Pa / 0 ... 100 – 5000 Pa  
 –0.2 ... +0.2 inH<sub>2</sub>O / 0 ... 0.4 – 20 inH<sub>2</sub>O  
 –5 ... +5 mmWC / 0 ... 10 – 500 mmWC

## Tolerable overload on one side

100 mbar  
 10'000 Pa  
 40 inH<sub>2</sub>O  
 1000 mmWC

For ± type max.:

100 mbar on P1, 4 mbar on P2  
 10'000 Pa on P1, 400 Pa on P2  
 40 inH<sub>2</sub>O on P1, 1.6 inH<sub>2</sub>O on P2  
 1000 mmWC on P1, 40 mmWC on P2

## Rupture pressure

2 x overload at ambient temperature  
 1.5 x overload at 70 °C

## Setting range

Zero point ±10% fs  
 Full scale 40 ... 100% fs

## Materials in contact with medium

Housing: Polycarbonate PC  
 Diaphragm: Silicone  
 Sensor: Al<sub>2</sub>O<sub>3</sub> (96%) / glass

## Temperature

Medium and ambient 0 ... +70 °C  
 Storage –10 ... +70 °C  
 No condensation

## Output Power supply

3-wire  
 0 ... 10 V 13.5 ... 33 VDC / 24 VAC ±15%  
 0 ... 20 mA 13.5 ... 33 VDC / 24 VAC ±15%  
 4 ... 20 mA 13.5 ... 33 VDC / 24 VAC ±15%

2-wire  
 4 ... 20 mA 11.0 ... 33 VDC

## Load

3-wire  
 0 ... 10 V > 10 kOhm  
 0 ... 20 mA < 400 Ohm  
 4 ... 20 mA < 400 Ohm  
 2-wire  
 4 ... 20 mA  $< \frac{\text{supply voltage} - 11 \text{ V}}{0.02 \text{ A}}$  [Ohm]

## Current consumption

At nominal pressure  
 3-wire  
 0 ... 10 V < 10 mA  
 0 ... 20 mA < 30 mA  
 4 ... 20 mA < 30 mA  
 2-wire  
 4 ... 20 mA 20 mA

## Dynamic response

Suitable for dynamic measurements  
 Response time < 10 ms  
 Load cycle < 10 Hz

## Electrical connection

Screw terminals for wire and stranded conductors up to 1.5 mm<sup>2</sup>, cable gland with built-in strain relief PG11

## Polarity reversal protection

Short circuit proof and protected against polarity reversal. Each connection is protected against crossover up to max. supply voltage.

## Protection standard

Without cover IP 00  
 With cover IP 54 or IP 65

## Pressure connections

Connection pipe Ø 6.2 mm

## Installation arrangement

Recommended and factory adjustment:  
 Vertical, with pressure connections downwards (± types forcible)

Horizontal with cover downwards.

Signal approximately 13 Pa higher than actual pressure

Horizontal with cover upwards.

Signal approximately 13 Pa lower than actual pressure

## Mounting

Mounting bracket (integrated in case)

## Display

Liquid-crystal, 3 digit

## Tests / Admissions

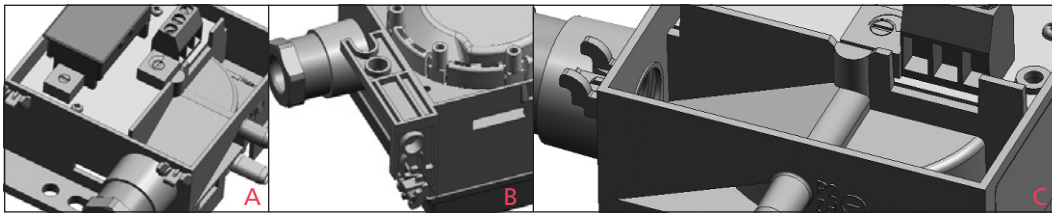
ETL  
 CE conform

## Weight

With display approx. 100 g  
 Without display approx. 90 g

## Packaging

Single packaging in cardboard



## Versions

- A – 2 potentiometers for full scale and zero point adjustment
- B – Housing with built-in fixing brackets
- C – Self-retaining screw in cover and angled surface for easy cable entry

## Accuracy

Transmitter Type Parameter	Unit	± 0.5 mbar	0 ... 1 mbar	0 ... 3 mbar	0 ... 5 mbar	0 ... 10–50 mbar
Tolerance zero point <sup>1)</sup>	max. % fs	± 1.0	± 1.0	± 0.7	± 0.7	± 0.7
Tolerance full scale <sup>1)</sup>	max. % fs	± 1.0	± 1.0	± 0.7	± 0.7	± 0.7
Resolution	% fs	0.2	0.2	0.1	0.1	0.1
Total of linearity, hysteresis and repeatability	max. % fs	± 3.0	± 2.0	± 1.0	± 1.0	± 0.6
Long term stability acc. to DIN IEC 60770	% fs	± 1.0	± 1.0	± 1.0	± 1.0	± 1.0
TC zero point <sup>2)</sup>	typ. % fs/10 K	± 0.2	± 0.2	± 0.2	± 0.1	± 0.1
TC zero point <sup>2)</sup>	max. % fs/10 K	± 1.0	± 1.0	± 0.5	± 0.4	± 0.4
TC sensitivity <sup>2)</sup>	typ. % fs/10 K	+ 0.3	+ 0.3	+ 0.2	+ 0.1	± 0.1
TC sensitivity <sup>2)</sup>	max. % fs/10 K	+ 0.6	+ 0.6	+ 0.5	+ 0.5	± 0.2

## With root-extracted output (2 ... 100% pressure)

Absolute error: (% of full scale)

TC zero point: (% fs) <sup>2)</sup>

$$0 \dots 1 \text{ mbar} \\ \text{max. } \pm 0.6 \sqrt{\frac{P_{fs}}{P}} + 1.5$$

$$0 \dots 3 - 50 \text{ mbar} \\ \text{max. } \pm 0.3 \sqrt{\frac{P_{fs}}{P}} + 1.5$$

$$\text{max. } \pm 0.6 \sqrt{\frac{P_{fs}}{P}} + 1.5$$

Test conditions: 25 °C, 45% RH, Power supply 24 VDC  
TC z. p. / TC s. 0 ... 70 °C

## Order code selection table

694. 9 X X X X X X X X X

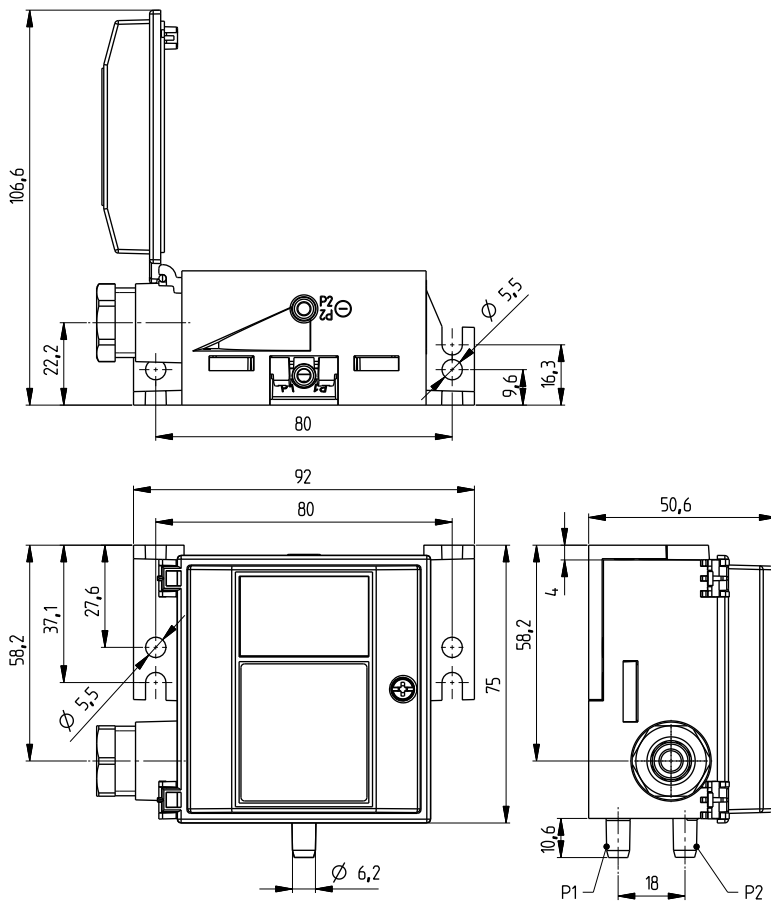
Pressure range <sup>3)</sup>	mbar (hPa)	Pa	mmWC (mmH <sub>2</sub> O)	inH <sub>2</sub> O																
	-0.5 ... +0.5	-50 ... +50	-5 ... +5	-0.2 ... +0.2	3	1														
	0 ... 1	0 ... 100	0 ... 10	0 ... 0.4	1	1														
	0 ... 3	0 ... 300	0 ... 30	0 ... 1.2	1	2														
	0 ... 5	0 ... 500	0 ... 50	0 ... 2	1	3														
	0 ... 10	0 ... 1000	0 ... 100	0 ... 4	1	4														
	0 ... 16	0 ... 1600	0 ... 160	0 ... 6.4	1	5														
	0 ... 25	0 ... 2500	0 ... 250	0 ... 10	1	6														
	0 ... 50	0 ... 5000	0 ... 500	0 ... 20	1	7														
Unit of pressure	mbar (hPa)									0										
	Pa									2										
	mmWC (mmH <sub>2</sub> O)									3										
	inH <sub>2</sub> O									1										
Output signal / Adjustment	Linear												1							
	Linear	Full scale and zero point adjustable by customer											2							
	Square root extracted												4							
	Square root extracted	Full scale and zero point adjustable by customer				1							3							
Output <sup>4)</sup> and power supply	0 ... 10 V	13.5 ... 33 VDC / 24 VAC ±15%		3-wire																1
	0 ... 20 mA	13.5 ... 33 VDC / 24 VAC ±15%		3-wire																3
	4 ... 20 mA	13.5 ... 33 VDC / 24 VAC ±15%		3-wire																4
	4 ... 20 mA	11.0 ... 33 VDC		2-wire																5
Display 3 digit	Without																			0
	In pressure unit chosen above													1						1
	In % fs																			2
Pressure connections / Pressure orifices	Connection pipe Ø 6.2 mm	without pressure orifice																		1
	Connection pipe Ø 6.2 mm	pressure orifice on P1																		2
	Connection pipe Ø 6.2 mm	pressure orifice on P2																		3
	Connection pipe Ø 6.2 mm	pressure orifices on P1 and P2																		4
Version	IP 54: Without connection kit																			0
	IP 54: With connection kit (metal), 90° angled including tube 2 m long (Fig. 1) <sup>5)</sup>																			1
	IP 54: With connection kit (plastic), straight including tube 2 m long (Fig. 2) <sup>5)</sup>																			2
	IP 65: Without connection kit																			3
	IP 65: With connection kit (metal), 90° angled including tube 2 m long (Fig. 1) <sup>5)</sup>																			4
	IP 65: With connection kit (plastic), straight including tube 2 m long (Fig. 2) <sup>5)</sup>																			5
Variation (optional)	Of pressure range or output signal																			
	Indicate W and state on order (e.g. 0 ... 9 mbar / Out 0 ... 10 V)																			

## Accessories

	Order number
Connection kit for vent duct (metal), 90° angled including tube 2 m long (Fig. 1) <sup>5)</sup>	104312
Connection kit for vent duct (plastic), straight including tube 2 m long (Fig. 2) <sup>5)</sup>	100064
DIN-rail mounting adaptor	112854
Calibration certificate	104551

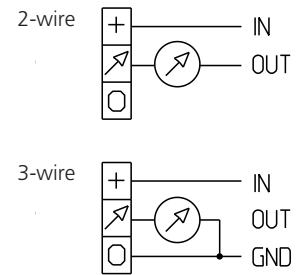
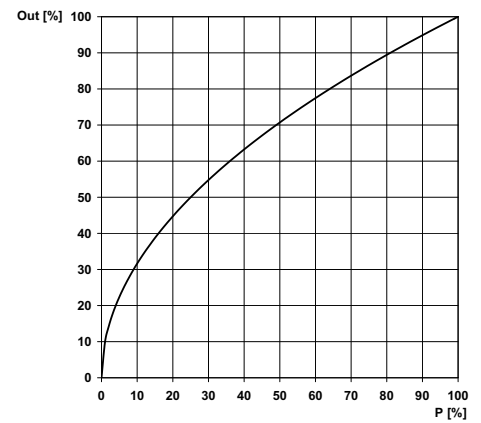
<sup>1)</sup> For changing diaphragm position see installation arrangement page 6  
<sup>2)</sup> TC = Temperature coefficient  
<sup>3)</sup> Other pressure ranges on request  
<sup>4)</sup> Other output signals on request  
<sup>5)</sup> See page 8



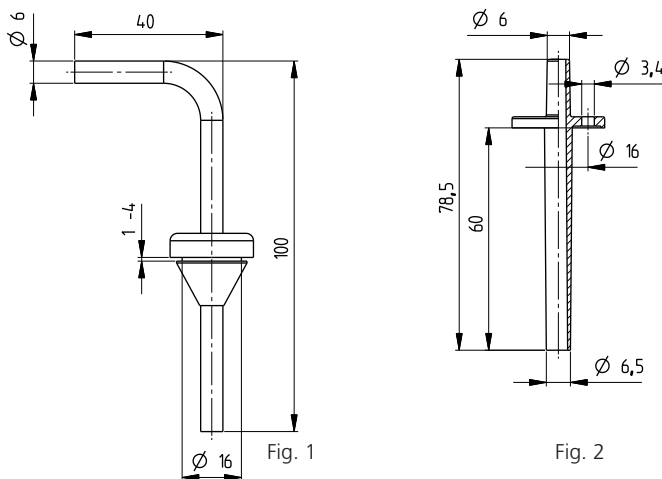


Root-extracted signal

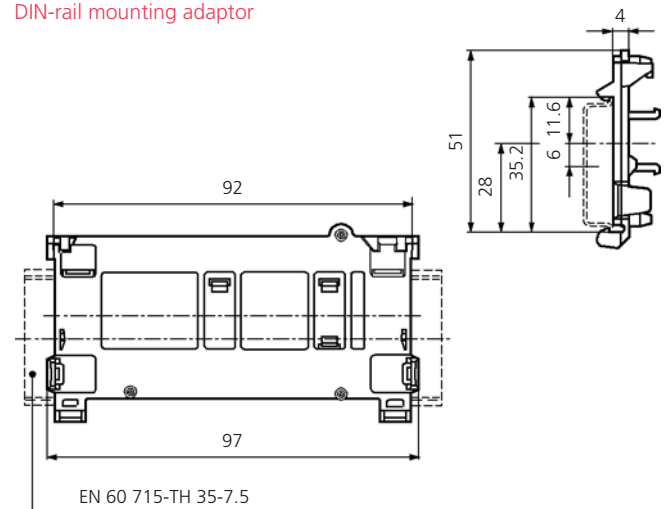
$$[\%] = 100 \cdot \sqrt{\frac{p[\%]}{100}}$$



## Accessories



## DIN-rail mounting adaptor



## Electromagnetic compatibility

CE conformity (EMC) by application of harmonised standards: EN 61000-6-2, EN 61000-6-3 und EN 61326

Interference stability	Test standard		Effect
Electrostatic discharge (ESD)	EN 61000-4-2	8 kV air / 4 kV contact	no effect
High-frequency electromagnetic radiation (HF)	EN 61000-4-3	10 V/m, 80 ... 1000 MHz	no effect
Fast transients (burst)	EN 61000-4-4	± 4 kV	no effect
Surge	EN 61000-4-5	Line-Line: ± 1 kV Line-Ground: ± 2 kV	no failure
Conducted HF interference	EN 61000-4-6	10 V, 0.15 ... 80 MHz	no effect
Magnetic fields	EN 61000-4-8	30 A/m, 50 Hz	no effect
Short time interruption and voltage fluctuation	EN 61000-4-11	60%	no effect
Interference emit	Test standard		Effect
Conducted interference	EN 55022 (CISPR 22)	0.15 ... 30 MHz	no emission
Radiation from housing		30 ... 1000 MHz, 10 m	no emission

# Huba Control

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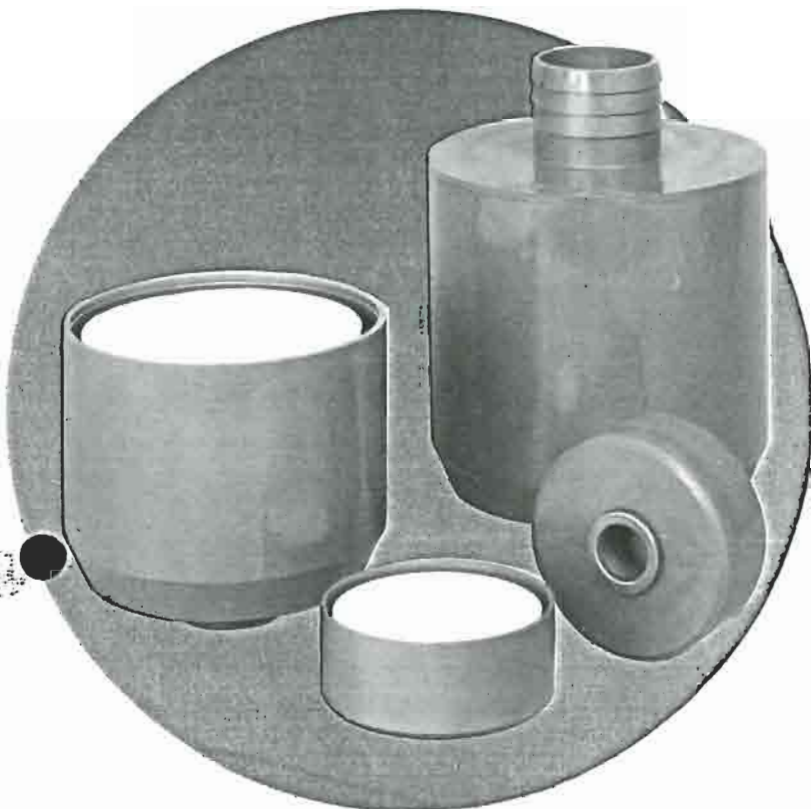
[www.hubacontrol.com](http://www.hubacontrol.com)

Technische Änderungen vorbehalten.  
Technical data subject to change.  
Sous réserve de modifications techniques.  
694.Edition 12/2007

# FILTRES POUR BOITES A GANTS ET ENCEINTES ÉTANCHES

FICHE  
FB - 1 - 01  
E

## FILTRES POUR BOITES A GANTS ET BOITIERS



### PAPIER FIBRE DE VERRE

EFFICACITÉS \* DOP et NaCl 99,99 %  
URANINE 99,98 %

DÉBITS 1 à 50 m<sup>3</sup>.h<sup>-1</sup>

PERTES DE CHARGE \*\* 40 à 250 Pa

SÉRIES 3201 à 3205 - 3211

### CHARBON ACTIF

DÉBITS 16 à 20 m<sup>3</sup>.h<sup>-1</sup>

SÉRIE 3603

BOITIERS FILTRES : SÉRIE 6202

\* DOP = aérosol de dioctylphthalate monodispersé Ø 0,3 µ (norme US MIL STD 282). NaCl = aérosol de chlorure de sodium Ø median en volume 0,35 µ (norme AFNOR X 44-013). URANINE = aérosol de fluoresceine sodée Ø median en volume 0,12 µ (norme AFNOR X 44-011). \*\* 1 Pa ≈ 0,1 mm CE.

## APPLICATIONS

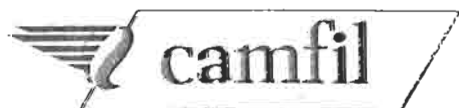
- Arrêt des poussières, bactéries et aérosols, équipement de boîtes à gants pour :
  - les industries :
    - nucléaire
    - pharmaceutique, etc.
  - les établissements hospitaliers.

## CONCEPTION

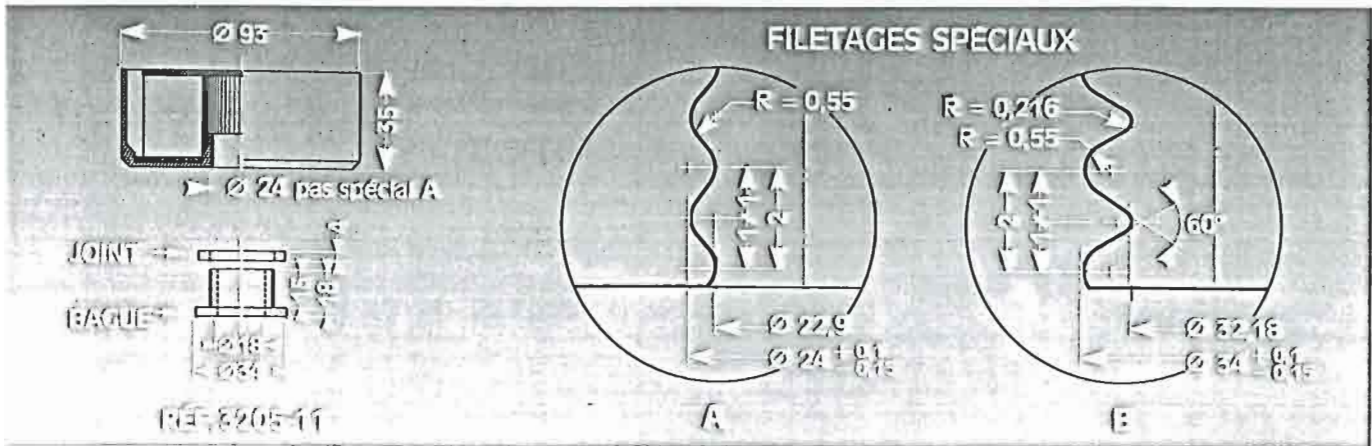
- Carter : en chlorure de polyvinyle (PVC) ou acier inoxydable.
- Media : papier fibre de verre ininflammable (comportement au feu classe M1) hydrofugé, plissé en nappe suivant un procédé breveté assurant l'écartement constant des plis.  
charbon actif imprégné 1% KI pour piégeage des radio-iodes.
- Lut : étanchéité de la nappe dans le carter réalisée au moyen d'un lut polyuréthane (PUE) ou chlorure de polyvinyle (PVC).
- Joint : néoprène ou viton.

## CONTROLE

Un contrôle de détection de fuite à l'aérosol d'uranine ou de brouillard d'huile est effectué systématiquement sur chaque filtre.

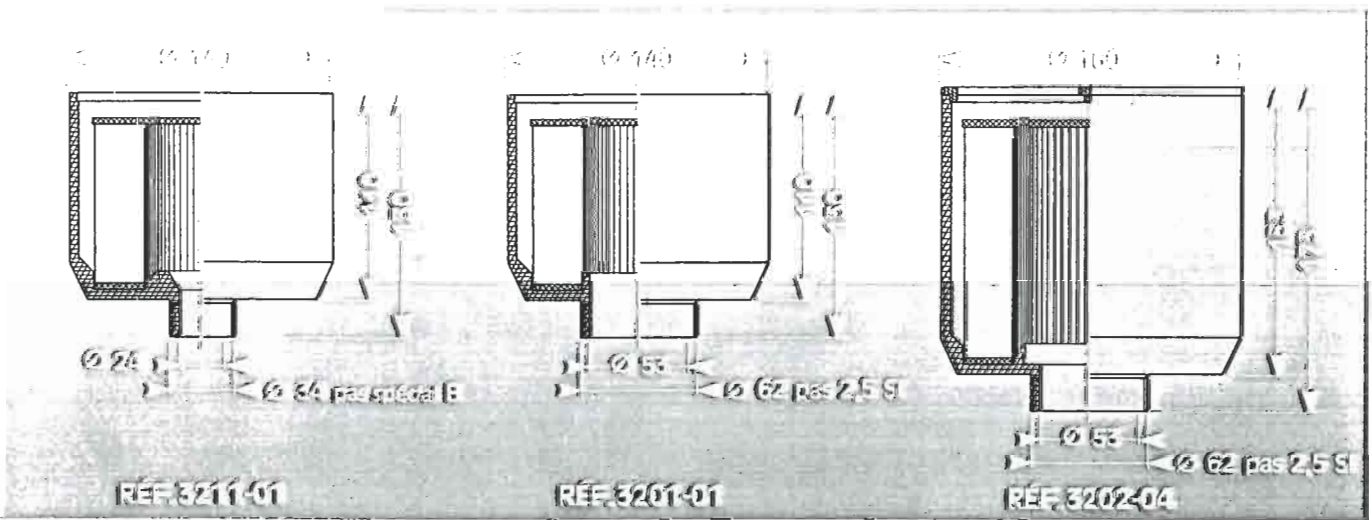


# FILTRES A CARTER OUVERT



DÉBITS m <sup>3</sup> .h <sup>-1</sup>	Δp Pa	CARTER	LUT	JOINT	t °C	FILETAGE	RÉFÉRENCES
1	60				80		<b>3205-11 (1)</b>
3	130	P/C	PUE	Néoprène	en	Pas 2 spécial A	
5	220				continu		

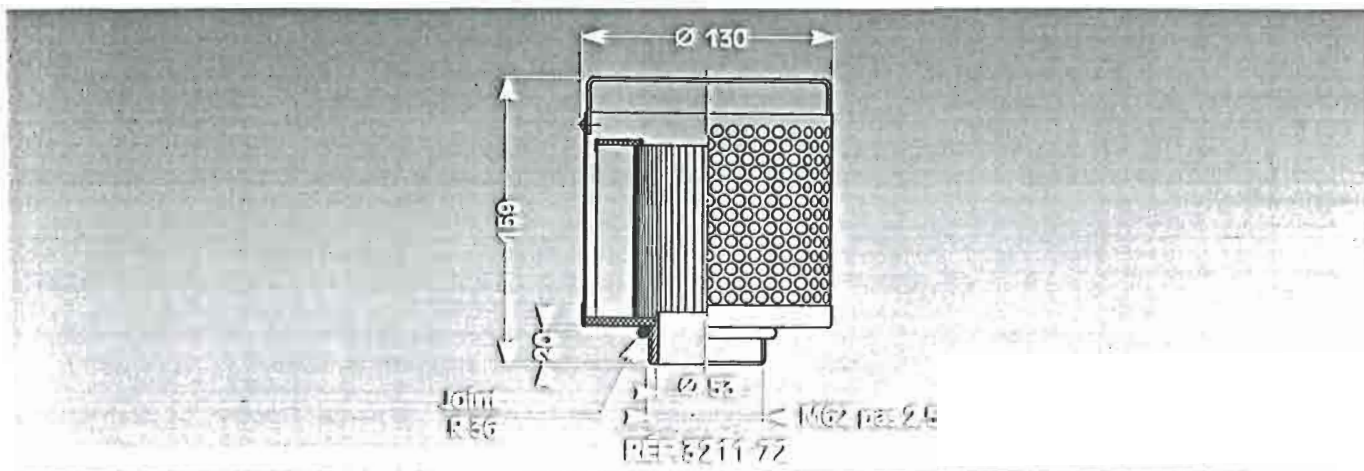
(1) Remplace les anciens modèles **3205-01** et **3205-51**. Filtre livré avec une bague PVC et avec joint.



DÉBITS m <sup>3</sup> .h <sup>-1</sup>	Δp Pa	CARTER	LUT	JOINT	t °C	FILETAGE	RÉFÉRENCES
10	70			Néoprène	80		<b>3211-01</b>
15	150	PVC	PUE	Ø 35/50	en	Pas 2 spécial B	
20	210			ép. : 5	continu		
10	50			Néoprène	80		<b>3201-01</b>
20	110	PVC	PUE	Ø 70/90	en	Pas 2,5 SI	
30	180			ép. : 5	continu		
20	70	PVC		Néoprène	80		<b>3202-04 (2)</b>
30	110	avec	PUE	Ø 70/90	en	Pas 2,5 SI	
50	200	croisillon		ép. : 5	continu		

(2) Remplace l'ancien modèle **3202-01** dont il diffère par l'adjonction d'un croisillon de préhension.

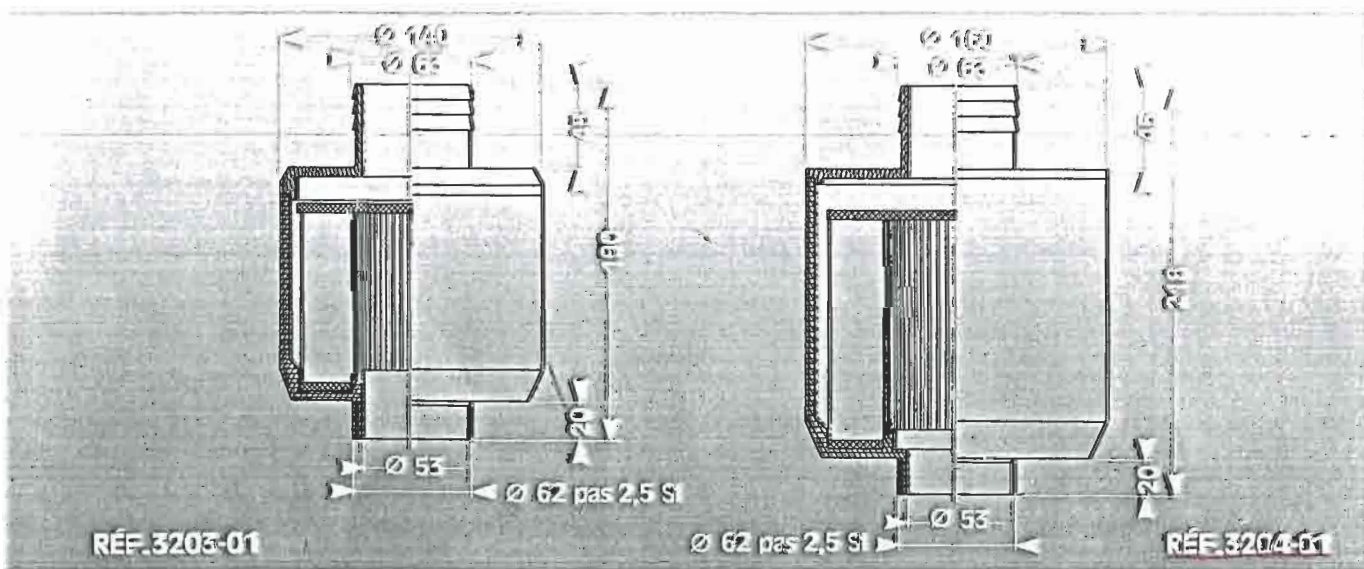




DÉBITS m <sup>3</sup> .h <sup>-1</sup>	Δp Pa	CARTER	LUT	JOINT	t °C	FILETAGE	RÉFÉRENCES
10	50	INOX			120		
20	110	Z2 CN 18-10	PVC	Viton	en continu maxi 200	Pas 2,5 ISO	3211-72
30	180	ou 304 L			pendant 1 heure		

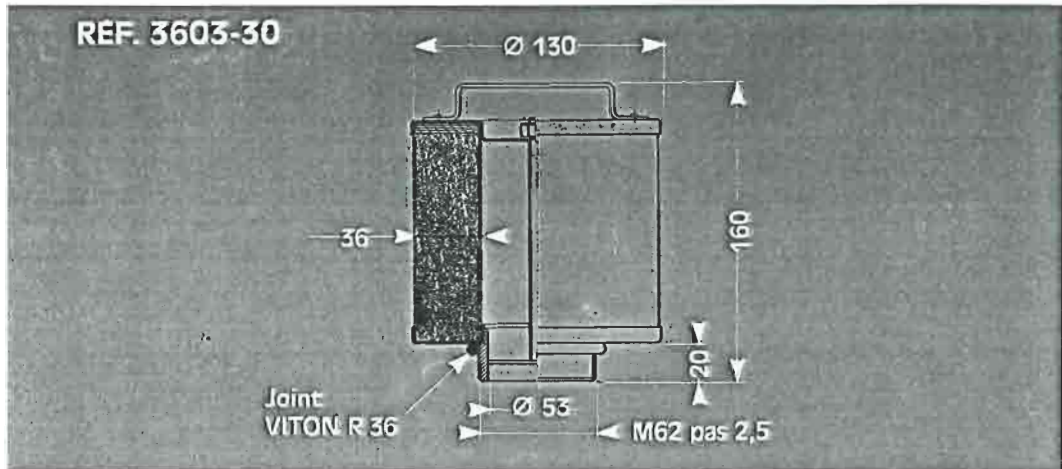
Ce filtre peut être monté dans un boîtier 6202-82 (voir page 4)

## FILTRES A CARTER FERME



DÉBITS m <sup>3</sup> .h <sup>-1</sup>	Δp Pa	CARTER	LUT	JOINT	t °C	FILETAGE	RÉFÉRENCES
10	40			Néoprène	80		
20	120	PVC	PUE	Ø 70/90	en	Pas 2,5 SI	3203-01
30	200			ép. : 5	continu		
20	80			Néoprène	80		
30	130	PVC	PUE	Ø 70/90	en	Pas 2,5 SI	3204-01
50	250			ép. : 5	continu		

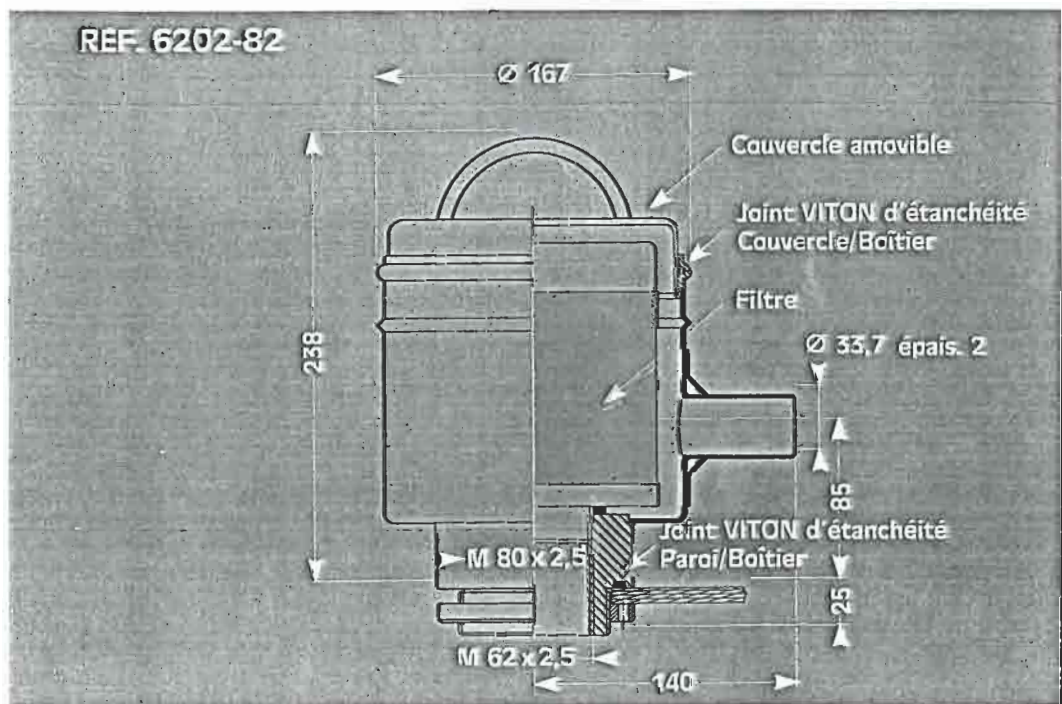
## FILTRE A CHARBON ACTIF



Filtre à charbon actif pour le piégeage des radio-iodes garni de charbon imprégné à 1 % KI. Construction en acier inoxydable Z2 CN 18/10 ou 304 L.

Volume de charbon litre		1,1
Temps de contact s	0,2	0,25
Débit m <sup>3</sup> .h <sup>-1</sup>	20	16
Perte de charge Pa	200	160

## BOITIER-FILTRE



Boîtier pouvant recevoir un filtre absolu 3211-72 ou un filtre à charbon actif 3603-30. Construction en acier inoxydable Z2 CN 18/10 ou 304 L. Référence du sac d'intervention : 1900-85

**SOFILTRA - CAMFIL**

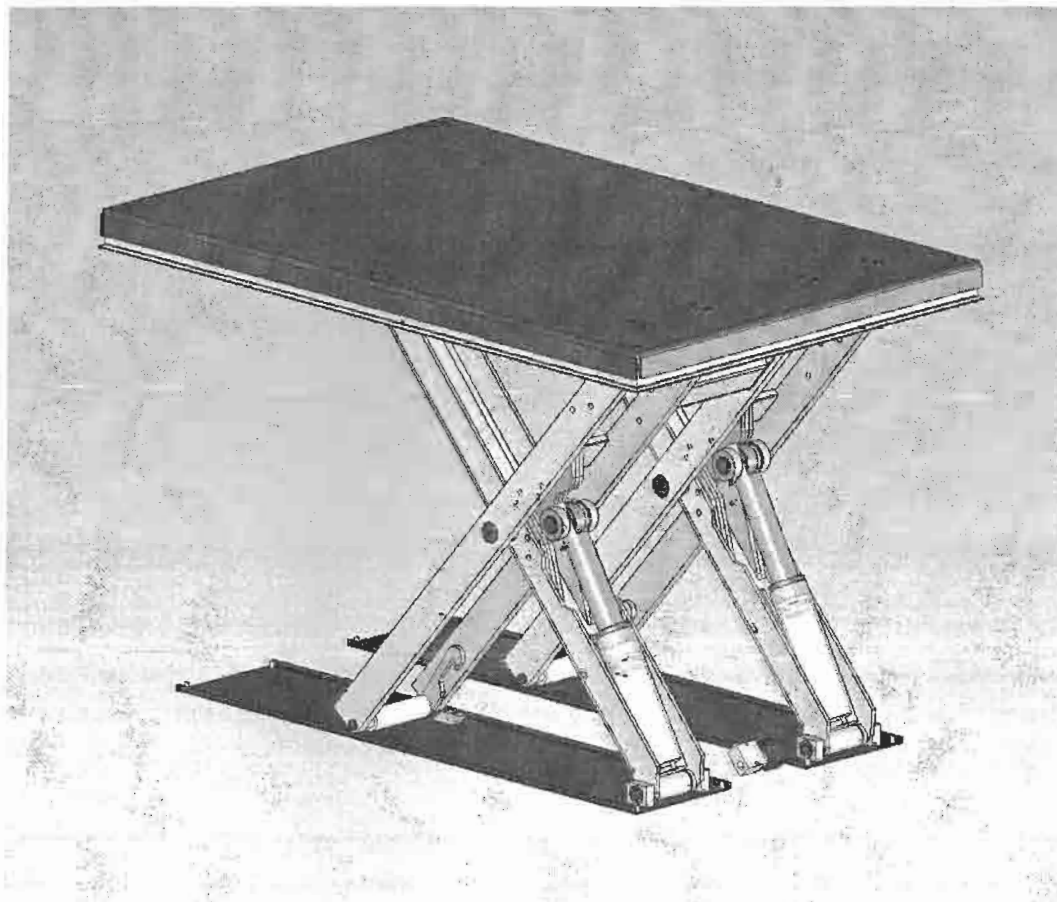
FILTRES A AIR

**TABLE ELEVATRICE**

**EXTRA PLATE**

**TYPE TIEP N 1.3 P/U/E**

**NOTICE de POSE et d'ENTRETIEN**



**NPE 05-95**

# SOMMAIRE

INSTALLATION ET MISE EN SERVICE

FONCTIONNEMENT

ENTRETIEN

CORRESPONDANCE DES HUILES

CONSIGNES DE SECURITE

SCHEMA HYDRAULIQUE

SCHEMA ELECTRIQUE

PIECES DE RECHANGE

DECLARATION CE



## INSTALLATION ET MISE EN SERVICE

- ① Contrôlez que la table élévatrice n'a pas été endommagée au cours du transport.
- ② Connectez les fils d'essai : 3 fils de phase (2 fils noirs et 1 fil marron)  
1 fil de neutre (bleu)  
1 fil de terre (jaune/vert)
- ③ Branchez les fils à leurs tensions respectives et actionnez la table vers le haut.  
Si table ne fonctionne pas bien que le moteur démarre, inversez 2 fils de phase.
- ④ Elevez la table au maximum. Retirez les fils d'essai et cablez les fils définitifs.

### IMPORTANT :

Veillez à ce que les chemins de roulement des galets des bras mobiles soient sur un sol parfaitement plat, lisse et propre.

**Il est recommandé de fixer la table au sol pour un meilleur fonctionnement.**

## FONCTIONNEMENT

Les tables extra plates ACI élévation montent grâce à l'action du moteur et de la pompe hydraulique, et descendent par gravité. (Le moteur ne tourne pas pendant la descente).

Un clapet piloté, monté directement sur une tuyauterie rigide entre chaque vérin assure l'arrêt en descente de la table en cas de rupture de flexible hydraulique.

Le bloc d'accouplement entre le moteur et la pompe comporte un limiteur de pression qui contrôle et interdit le fonctionnement de la table en cas de dépassement de la charge sur la table. Ne le déréglez jamais au risque d'endommager un organe hydraulique ou mécanique.

En fin d'utilisation placez de préférence la table élévatrice en position basse. Cette position est optimale tant pour la protection des organes hydrauliques et électriques de la table que pour la sécurité d'une façon générale.

Ne dépassez jamais les valeurs de charge nominale indiquées sur la plaquette de la table élévatrice.

### **IMPORTANT :**

**La charge doit être parfaitement centrée et répartie sur le plateau.**

## ENTRETIEN

Les tables élévatrices ACI. Élévation ne nécessitent pratiquement aucun entretien si ce n'est que les graissages indispensables au bon fonctionnement de votre matériel.

- Débarrassez l'environnement de la table de tous déchets qui pourraient nuire au bon fonctionnement de la machine, notamment lorsque celle-ci est placée en fosse.
- Dépoussiérez périodiquement l'ensemble de la table particulièrement :
  - Les chemins de roulement des galets,
  - Les composants électriques dans les coffrets.
- Remplacez les filtres hydrauliques à chaque vidange du réservoir.
- Contrôlez l'étanchéité du circuit hydraulique.
- Contrôlez le bon fonctionnement de la barre de sécurité située sous le pourtour du plateau.

**IMPORTANT:**

**VOTRE MACHINE EST EQUIPEE D'HUILE :**

**MARQUE : TOTAL**

**TYPE : EQUIVIS ZS 46**

**CORRESPONDANCES D'HUILES**

<u>MARQUES</u>	<u>TYPES</u>
HAFA.....	ISODEX 46
COFRAN.....	EQUIMECA
ANTAR.....	ANTAR HYDRAULIQUE
B.P.....	AGROLIC TC
ELF.....	HYDRELF DS 46
ESSO.....	UNIVIS N 46
FINA.....	HYDROFLO EP 34
IGOL.....	TICMA FLUID 46
MOBIL.....	MOBILFLUID 316
SHELL.....	SHELL TELLUS T 46
TOTAL.....	EQUIVIS ZS 46

## CONSIGNES DE SECURITE GENERALES

### PENDANT LES MANOEUVRES

Utiliser l'appareil dans des conditions compatibles avec ses performances.

Eviter tout mouvement brutal.

Surveiller tous les obstacles que l'appareil pourrait heurter.

En cas d'incident, stopper tous les mouvements, donner l'alarme et attendre l'intervention du responsable affecté au poste de sauvetage.

Eliminer toutes traces d'huiles ou graisses sur le plateau ou aux abords de l'appareil, qui pourraient favoriser les dérapages ou glissades.

### EN FIN DE SERVICE

Placer la table en position basse, dite position de repos.

Pendant les arrêts de longue durée, sectionner les postes de commande et couper l'interrupteur général.

Avertir le responsable de toute anomalie dans le fonctionnement ou l'état de l'appareil.

### LORS DES ENTRETIENS OU REPARATIONS

Décharger l'appareil si cela n'a pas été fait.

Monter la table en position haute, basculer les béquilles vers les butées du châssis et redescendre la table en appui sur ces béquilles.

Couper l'alimentation en énergie électrique et cadenasser le système.

Indiquer par un panneau votre présence, ex. "APPAREIL EN REPARATION"

### IL EST INTERDIT

D'utiliser l'appareil sans y être autorisé.

D'excéder la capacité maximale admise sur l'appareil.

De déporter la charge sur le plateau.

De neutraliser ou dérégler les dispositifs de sécurité.

De transporter du personnel avec les tables type extra plate.

NOTA : Ces consignes sont données à titre indicatif. Il appartient à l'utilisateur à adapter ou compléter ces consignes générales en fonction des usages particuliers et personnalisés.

**SHEMAS**

**HYDRAULIQUES**

**ET**

**ELECTRIQUE**

# TABLE ELEVATRICE EXTRA PLATE



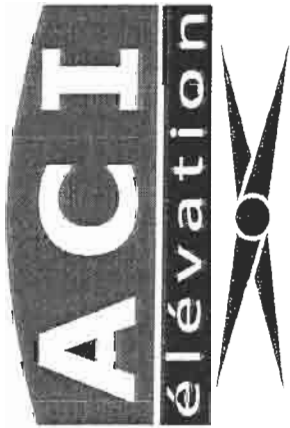
# ACI élévation

49, rue de Boulit

51110 ISLES SUR SUIPPE

IND	DATE	NOM	MODIFICATIONS	INDICE
Localisation TABLE + BAB + BS				INDICE
Client :			DESSINE PAR: DD	FOLIO
			N° de schéma : 1NTSCH00501	1
			DATE: 9/04/2009	





Type de machine

TIEP

Nombre de niveaux

AUCUN

Option(s)

STANDARD

SOCIETE:

ACI élévation

DATE:

28/04/2009

CLIENT:

NOROIT

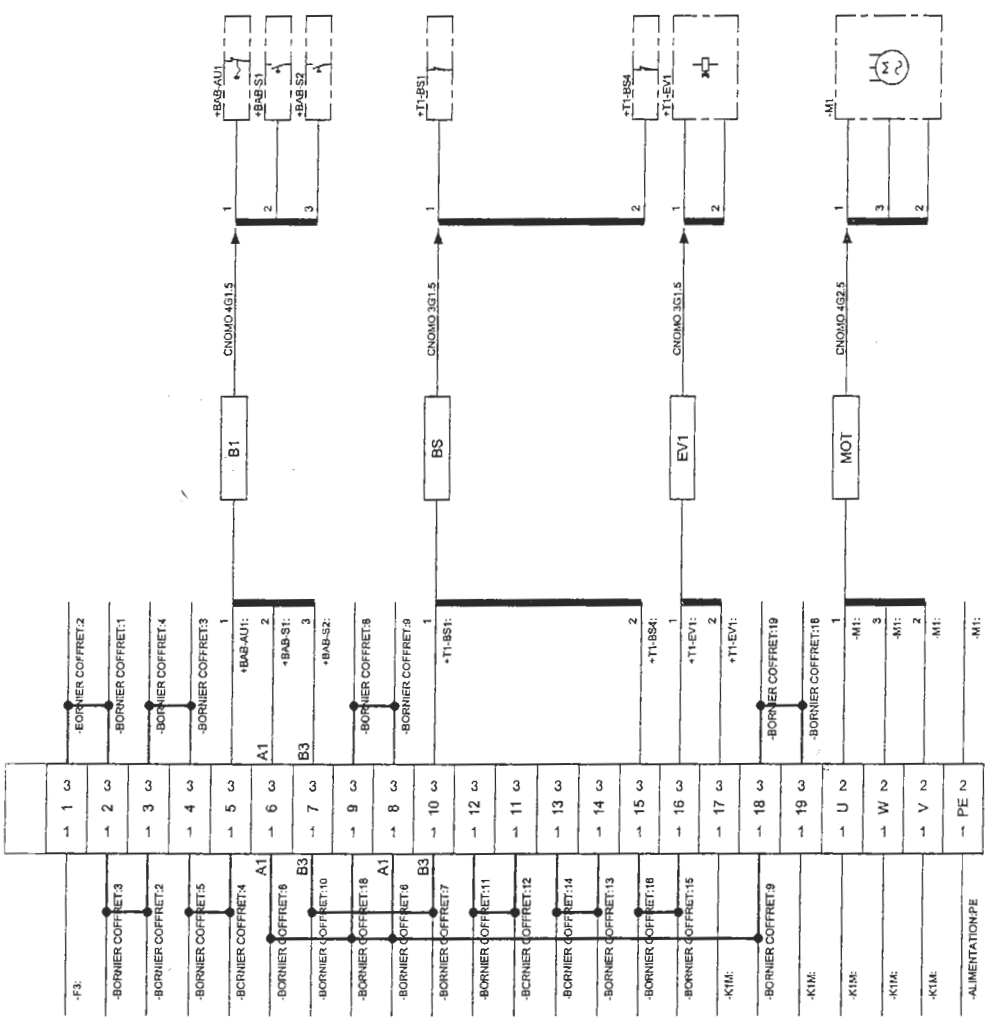
NUMERO D'AFFAIRE

19156

NUMERO DE SCHEMA

1NTSCH00501

BORNIER COFFRET

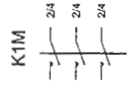
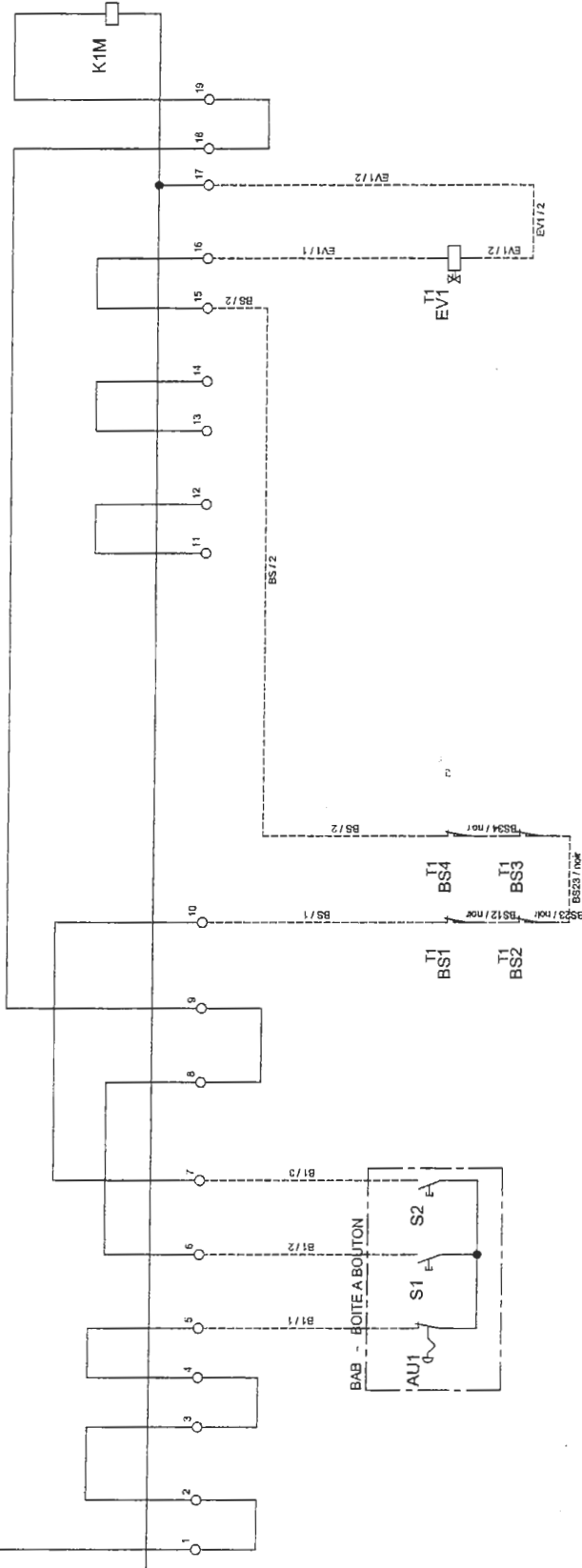


Folio suivant: 4

N° DE SCHEMA: 1NTSCH00501 Dossier: rdt484 avec TRACE ELEC PRO version: 3_05_09	Localisation Bornier BORNIER COFFRET			INDICE
	TYPE FOLIO: Dessin des borniers	IND	NOM	DATE
	MODIFICATIONS			FOLIO
	Dessiné le : 9/04/2009			4
	DD			

1 2 3 4 5 6 7 8 9 10

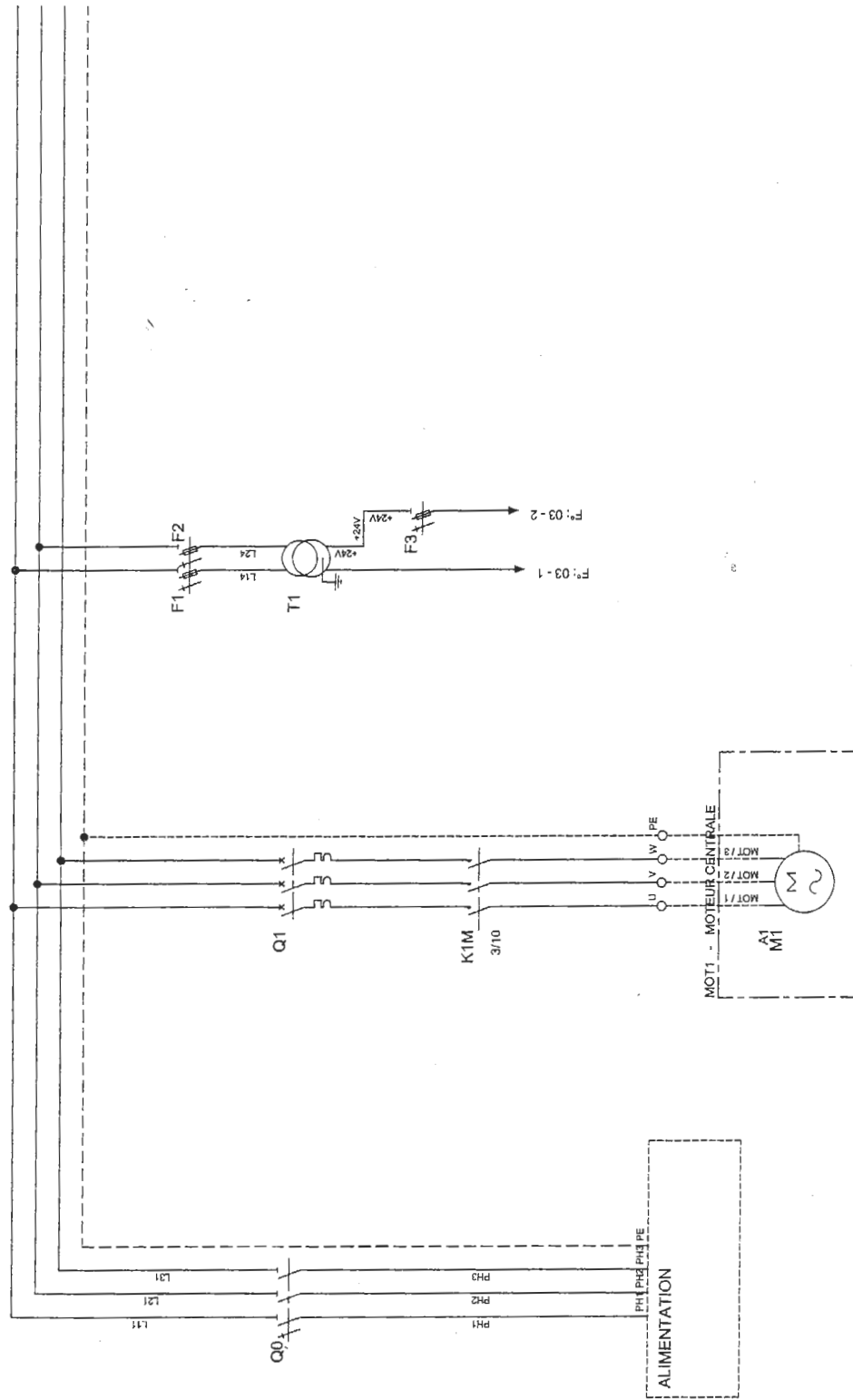
F: 02 - 6



Folio suivant: 4

N° DE SCHEMA : 1NTSCH00501	TYPE FOLIO : Schématique	Localisation COMMANDE				IND	NOM	DATE	MODIFICATIONS	FOLIO
		TABLE ELEVATRICE TABLE + BAB + BS				DD			Dessiné le : 9/04/2009	3
		INDICE								



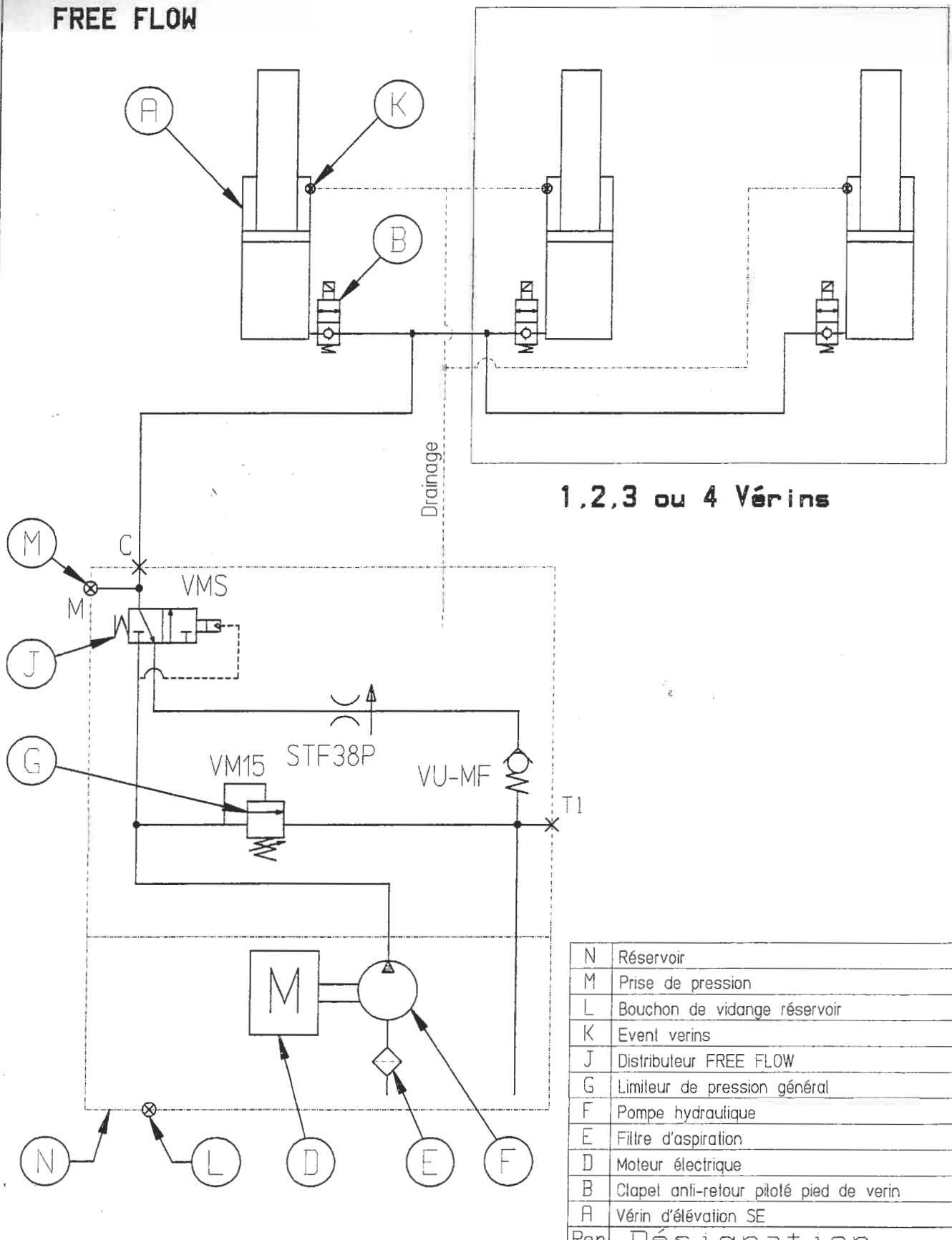


Folio suivant: 3

N° DE SCHEMA : 1NTSCH00501	TYPE FOLIO : Schématique	Localisation PUISSANCE				INDICE
		TABLE ELEVATRICE TABLE + BAB + BS				FOLIO 2
		IND	NOM	DATE	MODIFICATIONS	
		Dessiné par : DD				
		Dessiné le : 9/04/2009				



**FREE FLOW**

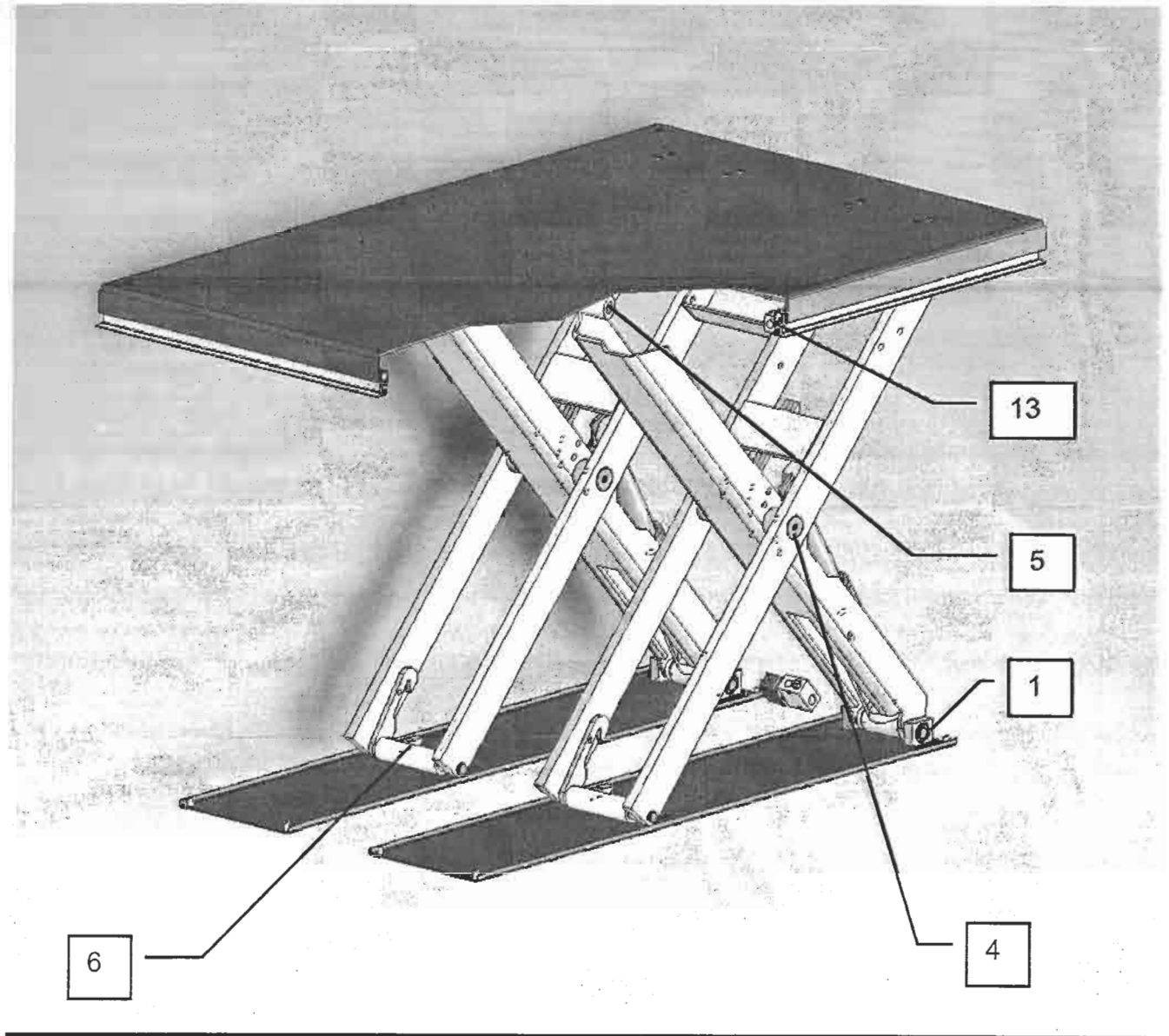


**1, 2, 3 ou 4 Vérins**

N	Réservoir
M	Prise de pression
L	Bouchon de vidange réservoir
K	Event verins
J	Distributeur FREE FLOW
G	Limiteur de pression général
F	Pompe hydraulique
E	Filtre d'aspiration
D	Moteur électrique
B	Clapet anti-retour piloté pied de verin
A	Vérin d'élévation SE
Rep	Désignation

<b>ACI ELEVATION</b> Rue de bouil 51110 isles sur suipe FRANCE Tél: 03 26 88 03 40 Fax: 03 26 88 03 38	Vérité par :	Visa contrôle	Réf. Affaire	Echelle :			
	le :			Format: A4V			
	Désignation	<b>SCHEMA HYDRAULIQUE</b> <b>TABLE 1, 2 ou 3 VERINS SE FREE FLOW</b>					
Dessiné par : AS	Plan N°	<b>1NTSCH00281</b>			07/08/07	A	
le : 18 / 04 / 05				N° modif	Date modif	Ind	

# PIECES DE RECHANGE



# PIECES DE RECHANGE

<b>PIECES DE RECHANGE TIEP N 1410 X 910</b>						
Qté	REP	DESIGNATION	MATIERE	CODE MAT	LONG	REP
2	1CC3001 A	<b>DEMI CHASSIS</b>				
4	2QJ0009	Bague TX 30 20				
2	1MS3008	<b>BRAS INTERIEUR EQUIPE</b>				
2	1UV3014 A	Galet superieur	Plastique POM Ø 40	2FQ0005	102	5
2	1AH3007	Axe de galet superieur	Etiré Ø 20	2FE0020	133	
4	2QJ0015	Bague TX 40 30				
2	1MS3009	<b>BRAS EXTERIEUR EQUIPE</b>				
2	1UV3015 A	Galet inferieur	Plastique POM Ø 40	2FQ0005	140	6
2	1AH3006	Axe de galet inferieur	Etiré Ø 20	2FE0020	233	
2	1BS3017	Entretoise de galet inferieur	tube Ø 26.9 ep 2.3	2FT5035	21	
4	1BS3018	Entretoise de galet inferieur béquille	tube Ø 26.9 ep 2.3	2FT5035	4	
2	1AG3005	axe intermediaire	étiré Ø 40	2FE0040	223	4
4	1BS3016 A	entretoise d'axe intermediaire	tube glacé 40x50	2FT5277	29,5	
2	1AH3001 A	Axe de point fixe bas	Etiré Ø 20	2FE0020	171	1
1		<b>EQUIPEMENT HYDRAULIQUE</b>				
1	2HC0522F	Centrale immergee REF : IM2/426/01-CL/12/S136/VF12/AK10SE				8
1	2HK0140	CLAPET (BLOC) VE1-NC-C - 24Vac - SANS BANJO - 3/8 - MONTAGE EN LIGNE 9676469B100				11
1		<b>EQUIPEMENT ELECTRIQUE</b>				
1	2EK0010	COFFRET - avec boite à boutons murale REF : 47419310				
2	2EH0007	FIN DE COURSE XCKP 2118 P16				13

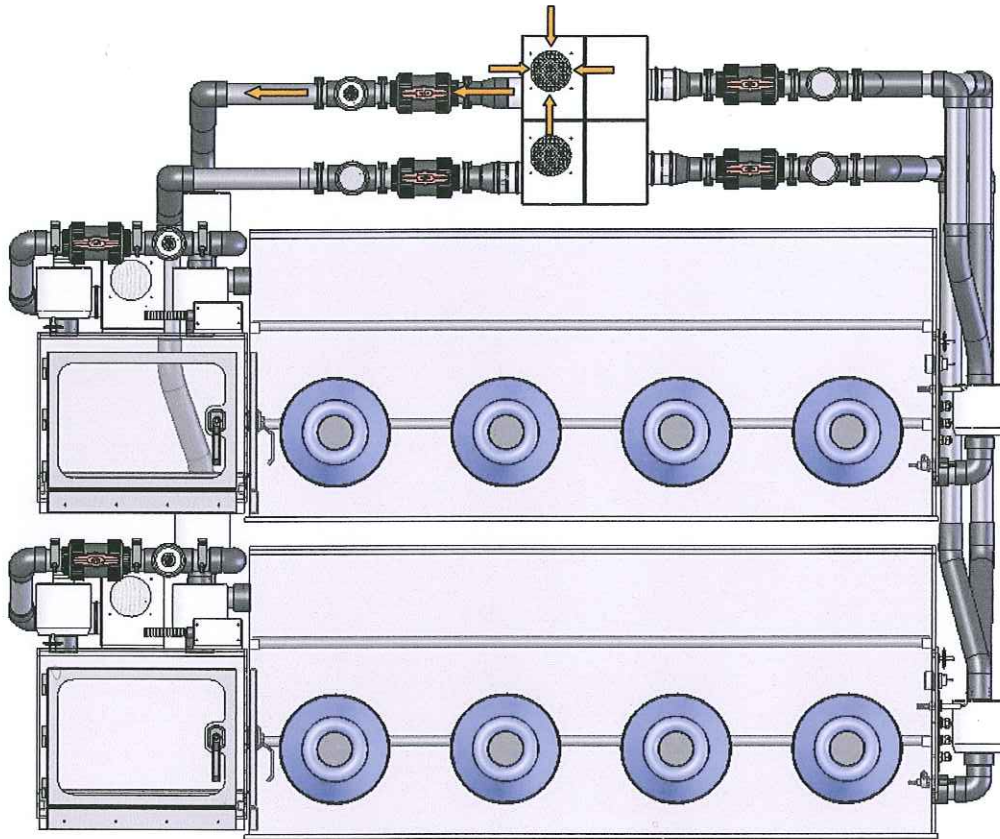




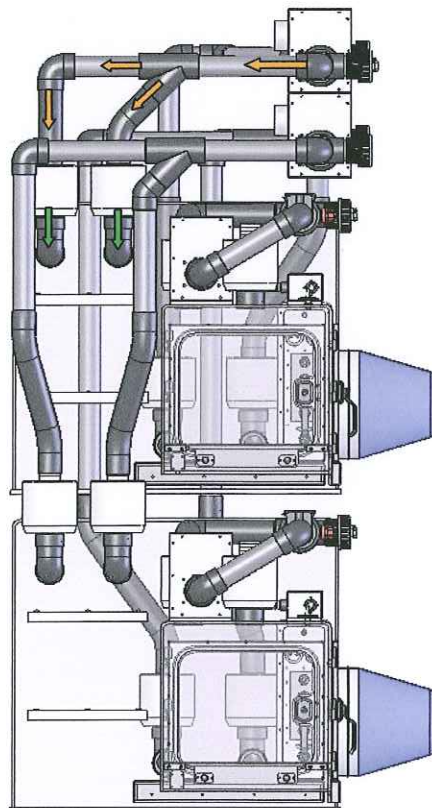
## 6. SCHEMATIC DRAWINGS

# PID Piping Instrument Diagram

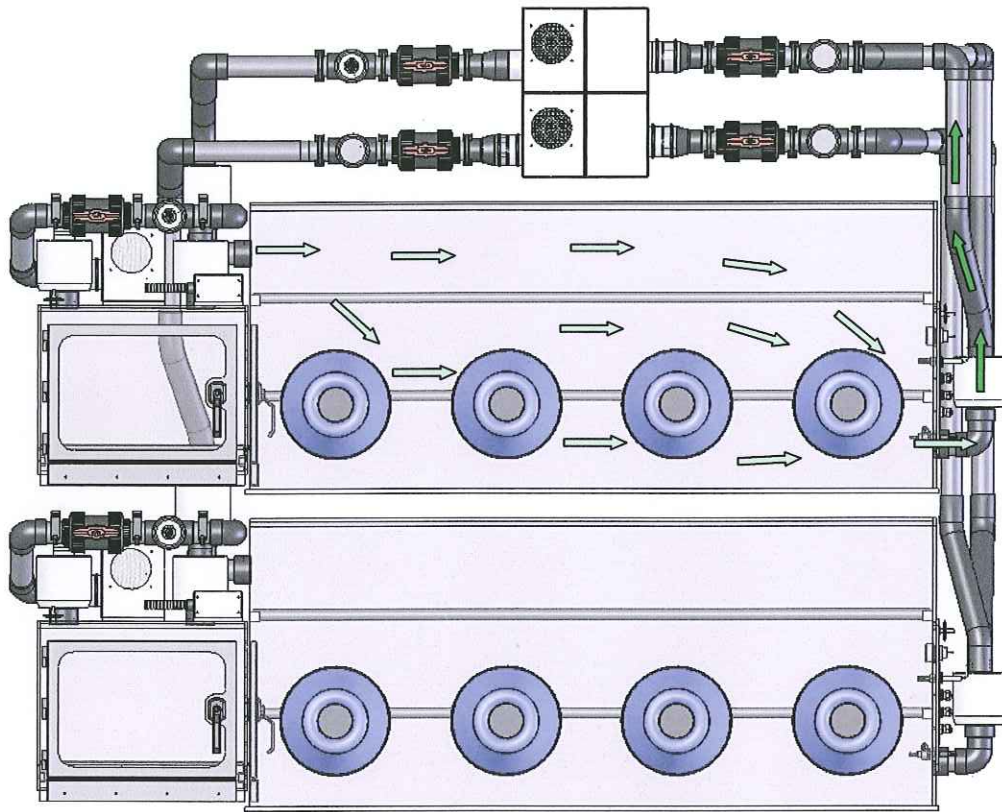
Up isolator  
1



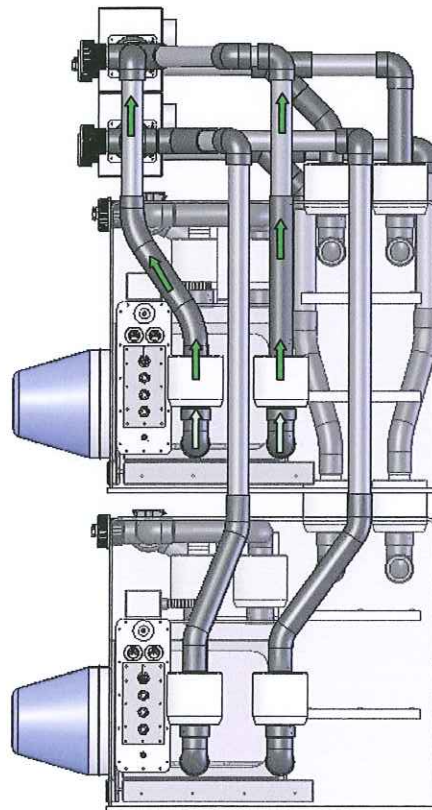
2



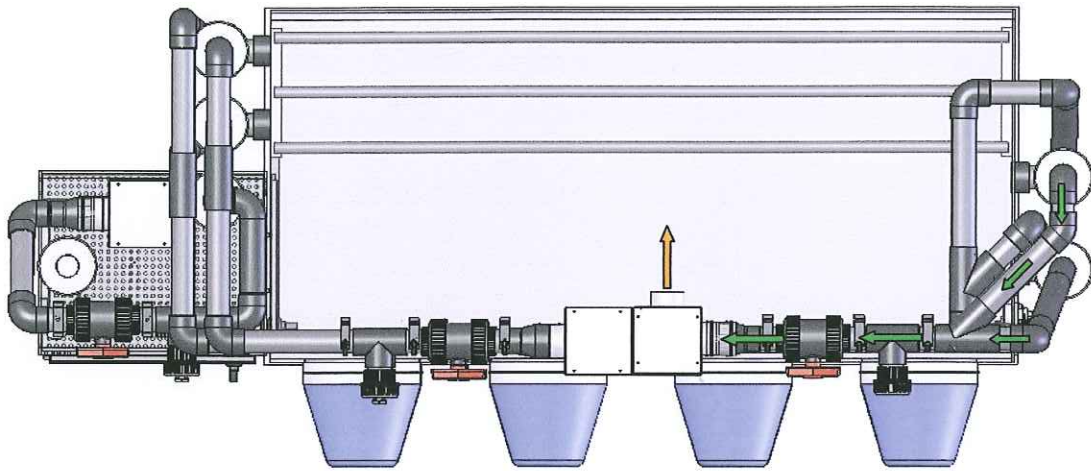
3



4



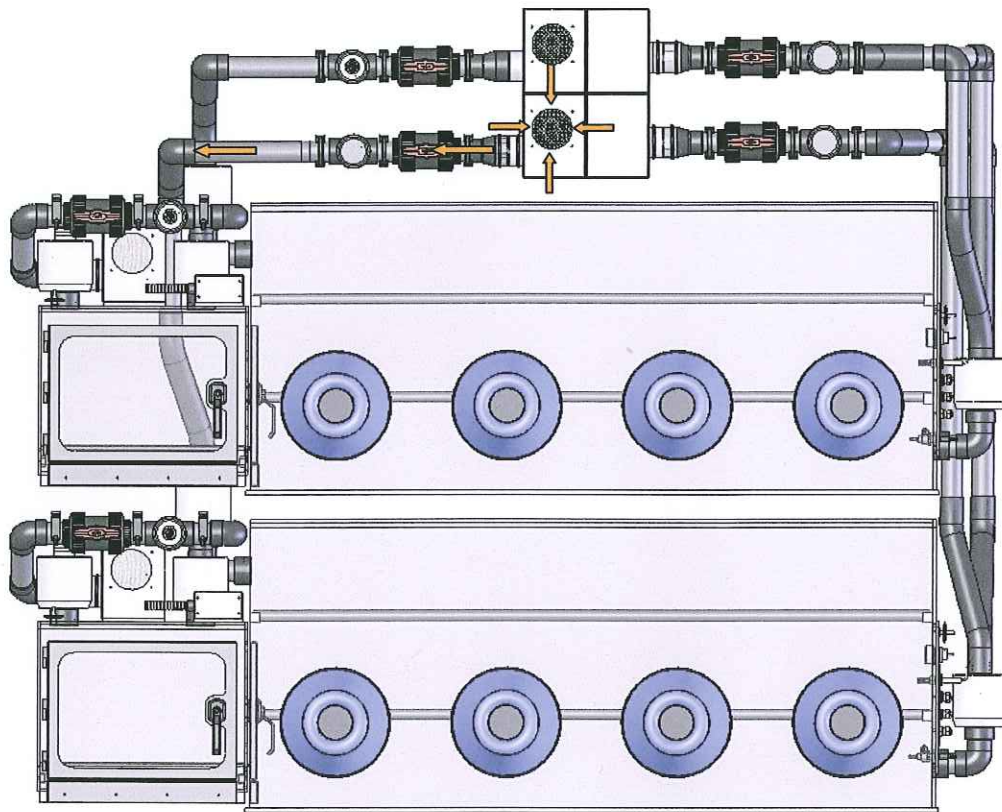
5



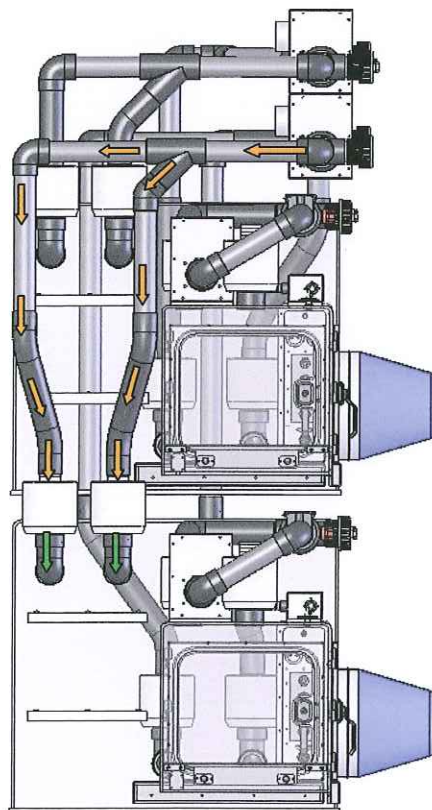


# Down isolator

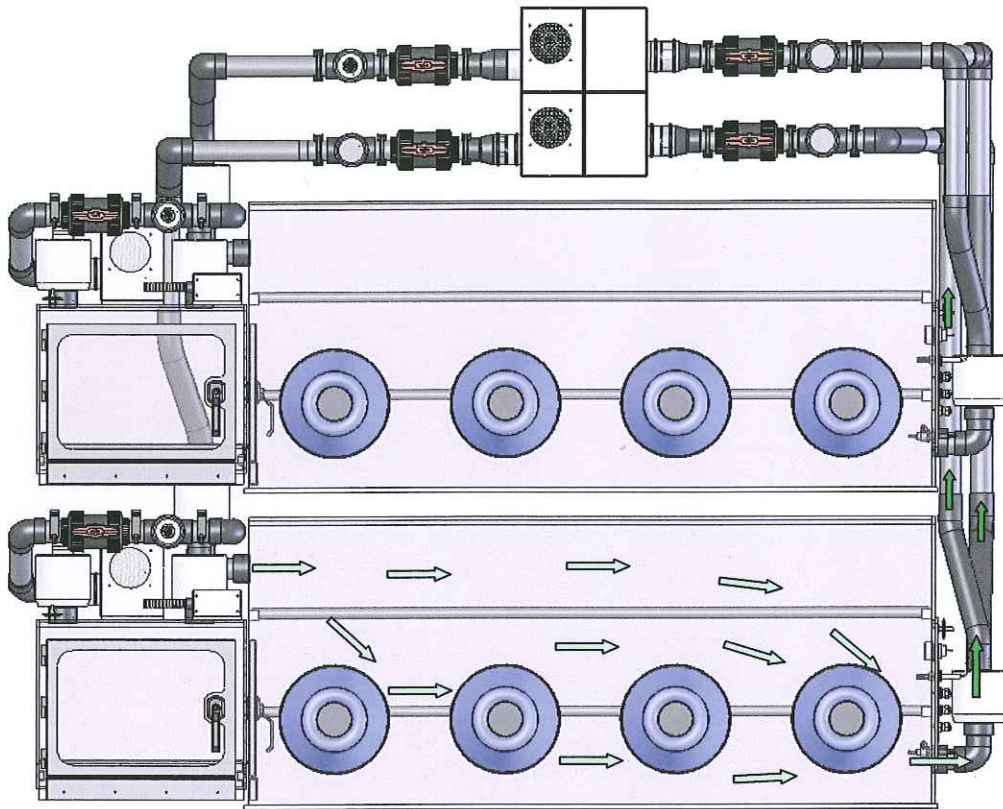
1



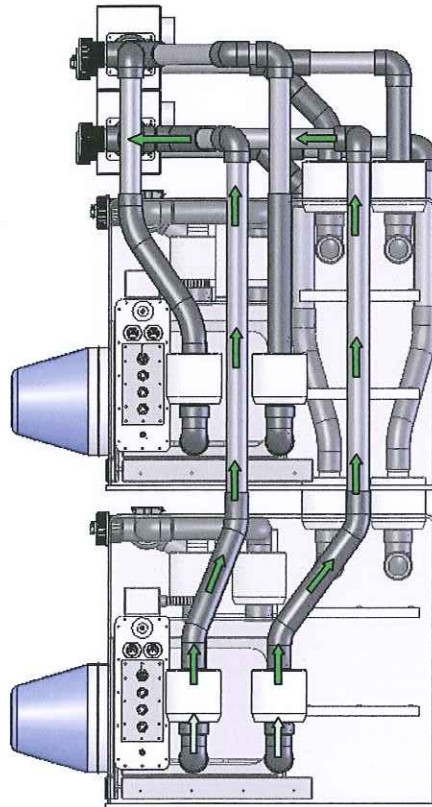
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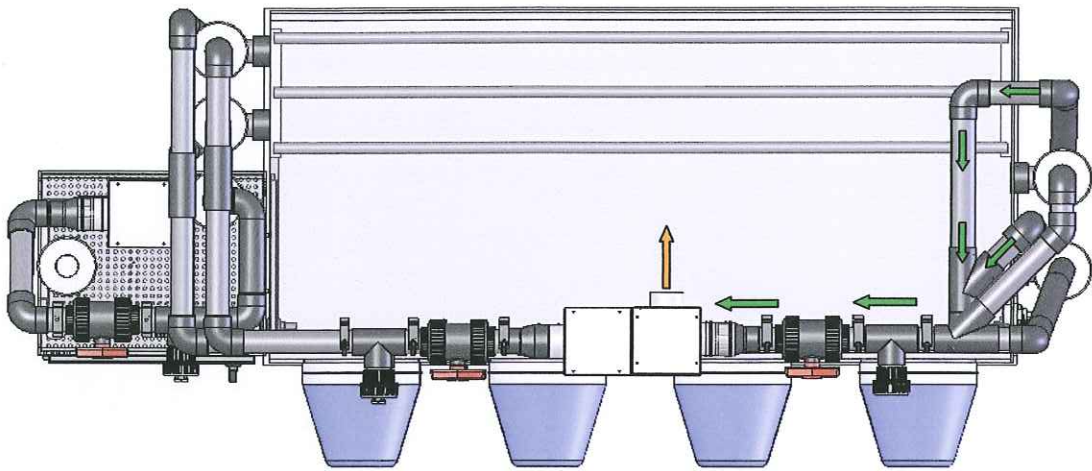
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4



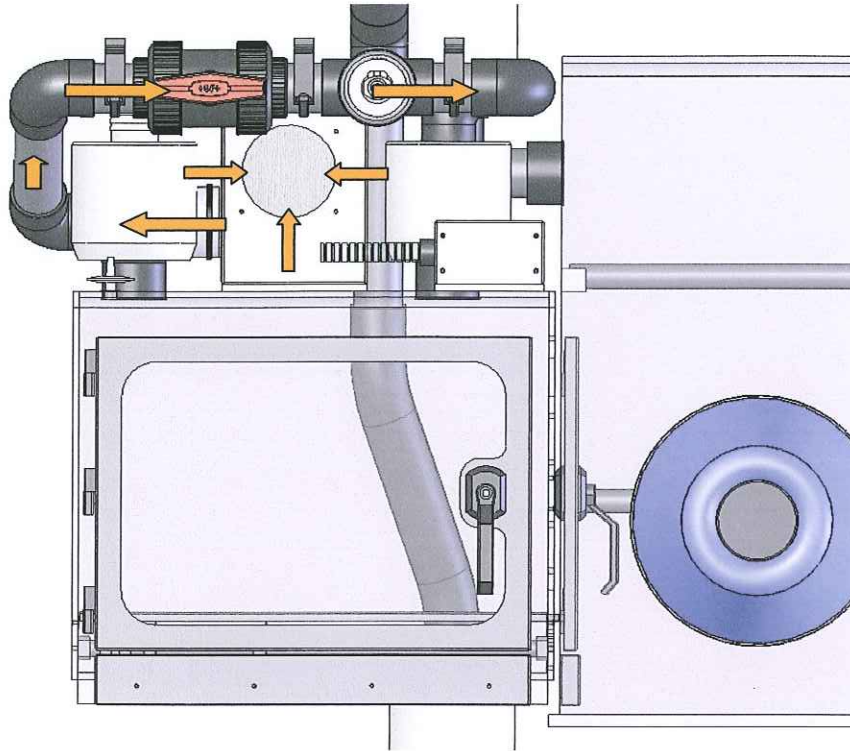
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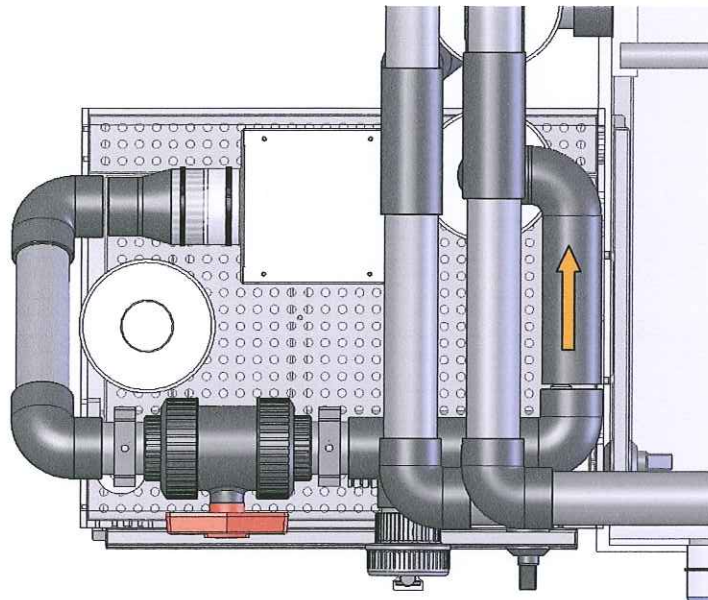


## Up and down transfer chamber

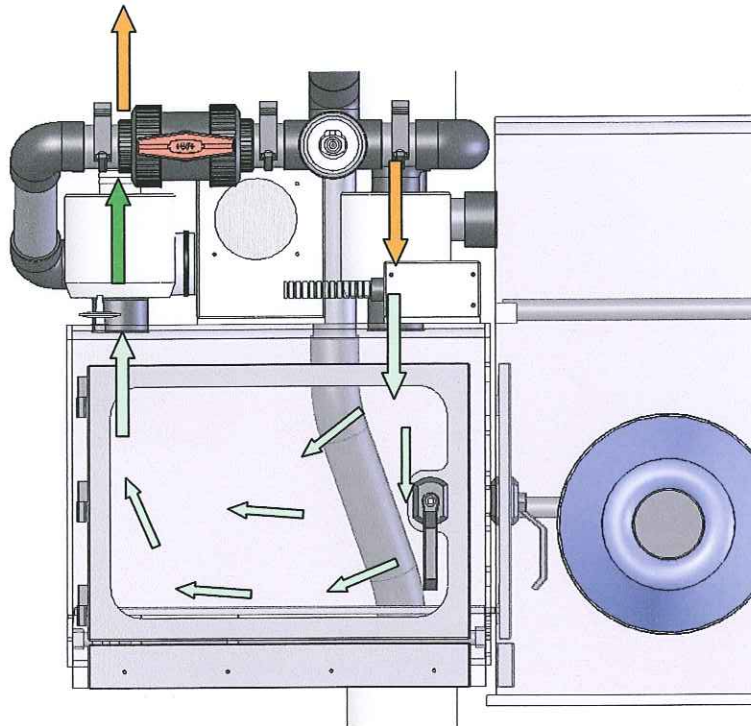
1



2



3





## 7. DECLARATION OF CONFORMITY



**DECLARATION DE CONFORMITE  
DECLARATION OF COMPLIANCE**



NOROIT déclare que le matériel désigné ci-après est conforme aux directives européennes suivantes :

*NOROIT declares that the instrument defined here below complies with the following European directives:*

**Basse tension - Low voltage**  $\iff$  73 / 23 CEE

**CEM - EMC**  $\iff$  89 / 336 CEE

En référence aux normes suivantes :

*With reference to the following standards:*

**EN 61010**

**CEM : 61000 - 6.1**

**61000 - 6.3**

**ISOLATEURS type IBOX**

REZE le : 10 janvier 2007  
Pascal SIDANER, Cogérant.

Client / Customer : NOROIT  
44400 REZE

Déclaration n°: 7280/09 du 1-juil.-09

N° de Commande/Order n° : 706420 DU 17/06/2009

N° du Bon de livraison : 585 du 2/07/2009  
*Packing list n°:*

N° de lot(s) : 10.27.2009  
*Fabrication lot n° :*

Nous déclarons que la fourniture a été fabriquée conformément aux exigences de votre commande ainsi qu'à nos fiches techniques produits, et matières.

*We declare that the goods of this purchase order have been manufactured in compliance with the specifications of your order and with the internal technical specifications of the products and material.*

Les opérations des autocontrôles et du contrôle final sont conformes à nos critères d'acceptation.  
*Self-control and inspection are true to our acceptance criteria.*

CONTROLE FOURNISSEUR  
SUPPLIER'S CONTROL

Responsable Qualité : Didier Aguesseau  
*Quality manager :*  
Livry-Gargan le : 1er juillet 2009  
Signature.





<b>PLASTUNION</b> 40, allée des Charmilles 93190 LIVRY-GARGAN	<b>MARQUAGE RECOMMANDATIONS</b> <b>GARANTIE DE STOCKAGE</b>	DE n° 01 rév 00
		décembre 03

### PRODUITS CONCERNES

- Accessoires souples de « BAG » (boîte à gaht) et d'isolateurs : sacs de « BAG » manchettes, hémiscaphandre, etc. ...
- Films souples : PVC (polychlorure de vinyle), PUR (polyuréthane), PVC enduit « type «KARTSUP» et PE / EVA (polyéthylène / Éthylène vinyle Acétate).

### MARQUAGE

Moyen et méthode

- TRANSFERT THERMIQUE.  
Traçabilité :

PLASTUNION		
REF - 02.31		
LOT - 120 - 48 - 97		
1	2	3

1) Lot matière 1 <sup>ère</sup> (film) <sup>(a)</sup>
2) Semaine de fabrication
3) Année de fabrication

Exemple spécifique <sup>(b)</sup>

Nom ou logo du CLIENT
REF - 02.31
LOT - 48 - 97

- (a) Non imprimé sur le produit dans le cas de l'emploi de plusieurs matières. La traçabilité est reproduite sur la fiche « production / suivi qualité » du produit.
- (b) Les exigences particulières des clients sont imprimées sur le produit. La traçabilité est reproduite sur la fiche « production / suivi qualité » du produit.

Autre exemple spécifique <sup>(b)</sup>

Logo CLIENT
13011000115 / 15.498
LOT - 14 - 2003

Semaine de fabrication  
Année de fabrication

### RECOMMANDATIONS

#### Utilisation :

- ⇒ Produits en PVC et PE/EVA : local sec et aéré (15°C à 40°C).  
Bonne tenue chimique. Soudure haute fréquence aisée - scellage par impulsion possible.
- ⇒ Produits en PUR : local sec et aéré (-15°C à 30°C) - Pas de contact direct avec des produits acides concentrés. Très bonne résistance mécanique et bonne tenue aux huiles et essences.  
Soudure HF et impulsions aisées.

#### Nettoyage :

- ⇒ Au moyen d'un mélange éthanol / eau (1/1) ou d'eau savonneuse à 30° C sans abrasif.  
L'utilisation de solvants et d'eau de Javel sont interdites.
- ⇒ Nettoyage avec des bactéricides (se conformer aux prescriptions du fabricant).

### GARANTIE DE STOCKAGE

PVC et PE/EVA : stockage des produits 24 mois à l'abri de la lumière, carton d'origine fermé et stocké dans un local sec et aéré ( 15°C à 30 ° C).

PUR : stockage des produits 48 mois, à l'abri de la lumière, carton d'origine fermé et stocké dans un local sec et aéré (- 15°C à 50°C).



77-81, BOULEVARD DE LA RÉPUBLIQUE - 92257 LA GARENNE-COLOMBES CEDEX

TÉLÉPHONE : 01 46 52 48 00 - FAX : 01 47 60 17 81  
 INTERNATIONAL : 33 1 46 52 48 00 - FAX : 33 1 47 60 17 81  
 EXPÉDITIONS

USINE ET MAGASIN / Factory and warehouse : ROUTE D'AVRIGNY  
 Z.I. DE SAINT-MARTIN-LONGUEAU - 60700 PONT SAINT-MAXENCE

TéL. : 03 44 29 33 92 ou 84  
 Fax : 03 44 29 33 46

ADRESSE DE LIVRAISON / Delivery address

NOROIT  
 2 RUE ROBERT SCHUMAN  
 44408 REZE  
 France

ADRESSE DE FACTURATION / Invoicing address

NOROIT  
 REZE CREATIC  
 2 RUE ROBERT SCHUMAN  
 44408 REZE  
 France

TRANSPORTEUR  
 Forwarding agent

T06  
 GRAVELEAU

RÉCÉPISSÉ  
 Receipt

RÉF. INTERNES  
 Internal ref.

PORT / Transport  
 EMBALLAGE / Packaging

03/09/2008

DATE D'EXPÉDITION / Shipping date

A.R.C. N° / Our ref.

03/09/2008

RÉF. CLIENT / Your ref.

C-L00C-0124652

CLIENT N° / customer no

706269

PRÉPARÉ LE / prepared

08/09/2008

DU / Dated

01/06/2008

SECTEUR N° Sales area

103

QTE COMMANDÉE  
 Quantity ordered

5 10.00

RÉF. ARTICLE  
 Item no

52040100

DÉSIGNATION  
 Description of goods

FILTRE BOITE A GANT 840902

DÉLAI PRÉVU  
 Delivery time

03/09/2008

QUANTITÉ LIVRÉE  
 Quantity shipped

10.00

N° LOT  
 Batch Nr

103

Ces produits ont été fabriqués et contrôlés conformément à nos systèmes de management de la qualité certifiés ISO 9001.

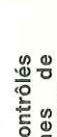
Products have been made and checked in conformance with ISO 9001 approved quality management systems.

Responsable Qualité Fournisseurs :  
 Supplier quality manager :

Nom / Name : Myriam Tryjefaczka

Fonction / Title : Responsable Qualité

Bon pour expédition





# DECLARATION "CE" DE CONFORMITE

## MACHINE NEUVE SOUMISE A AUTO CERTIFICATION

Le fabricant:

Nom: **ACI élévation**  
Adresse: **49, rue de Boulton**  
**51110 Isles sur suippe**  
**France**

Déclare que la machine décrite dans la notice d'instructions et désignée ci-dessous:

### TABLE ELEVATRICE

Type:

**TIEP 1,3T C800 12.07 1X 1410X910 P**

Charge Nominale:

**1300 kgs**

N° de série

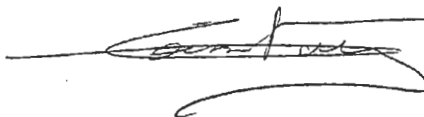
**19145**

Est conforme aux exigences essentielles de sécurité et de santé, qui la concerne,

- de la directive européenne n° 98/37/CE du 22 juin 1998
- de la norme EN 1570
- de la directive 73/23/CEE du conseil, du 19 février 1973, concernant le rapprochement des législations des Etats membres relatives au matériel électrique destiné à être employé dans certaines limites de tension
- de la directive 89/336/CEE du conseil du 3 mai 1989 concernant le rapprochement des législations des Etats membres relatives à la compatibilité électromagnétique

### Signataire ayant pouvoir pour engager le déclarant

Nom : Claude COURTIN  
Fonction : DIRECTEUR  
Lieu et date de signature : Isles, le 28 avril 2009





## 8. SAT PROTOCOLS

- IQ Protocols
- IQ Protocols
- Leak test protocol



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Fax : 332.51.70.20.25  
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[www.noroitlabo.com](http://www.noroitlabo.com)

**SAT PROTOCOL**  
**Installation qualification**  
**ISOLATORS ESA BARCELONA**

Index	Description	Editing	Date	Signature
1	Creation	Julien VICTOR	07/06/09	

**Approval of protocol**

Company	Function	Name	Date	Signature
ESA / UAB				

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**1 PURPOSE: Isolator static control,**  
**Serial number :** 20090702000.  
**Localisation :** Barcelona.

## **2 EQUIPMENT DESCRIPTION :**

Equipment :  
Isolator ESA Barcelona type.

### **Overall description :**

The I-BOX isolators are rigid enclosures for an optimal containment of animals. I-BOX isolators are the best solutions to keep the animals in defined sanitary conditions. This isolators ensure total protection of the user, the manipulation and the environment, by means of :

- Absolute tightness of the chamber.
- Positive pressure inside the chamber.
- High efficiency filtering (99.99% for 0,3 µm particles)
- Physical barrier (fiberglass body and gloves) between the user and potentially dangerous handled materials.

It also enables operation in a sterile environment.

The performance of this type of equipment depends not only on the instrument itself but also upon the following parameters:

- The user: Use of isolators must be reserved for qualified personnel having received suitable training.
- Servicing: the filters efficiency and the air cleanness measurement must be checked regularly and at preferably, once a year.

### **Characteristics :**

- External dimensions : length x width x height : 2m36 x 1m10 x 3m.
- Construction : Stainless steel 316 L.

### **Equipments :**

- 2 units of 4 glove isolators. They are located one upon the other.
- Each isolator has a transfer chamber.
- The pressure is created by fans.
- Anemometers control the airflow.
- Sensors measure temperature, hygrometry and pressure.
- Each air intake features a pre-filter.
- HEPA filter.
- 2 control panels, located :
  - On a console, next to the isolators.
  - On a lift table console, next to the isolators.

The isolators control panel features :

- Temperature, hygrometry, pressure and airflow displays. One for each measurement and for each isolator.
- A green LED, which indicates the correct value, for each variable and each isolator.
- A red LED, which indicates the value in default, for each variable and each isolator.
- Two trimmers control the airflow for each isolator and another two control the pressure for each isolator.
- "on/off" switches start / stop pressure and airflow fan. One for each variable and for each isolator.
- An electronic key, switches on / off the unit.

### 3 SIGNATURES ARRAY :

Company	Function	Name	Date	Signature
NOROIT				
ESA / UAB				

### 4 STATIC SAT TESTS EXECUTION

The execution of the static SAT tests is performed on the site of the:

Departament de Enginyeria Química  
Escola Tècnica Superior de Enginyeria (ETSE)  
Universitat Autònoma de Barcelona  
Campus de Bellaterra, Barcelona.

They are performed by Noroit and controlled by Ms. Munganga.

### 5 STATIC TESTS LIST

Test 1 : Controls the attached documentation.

Test 2 : Controls the components and the compliance with specifications.

Test 3 : Controls the keyboard.

Test 4 : Controls the electrical installation.

Test 5 : Controls that there is no visual default.

### 6 NON-COMPLIANCE HANDLING

In case of non compliance, for a test :

- In the array, chapter 9, « Results and observations summary », indicate the number of the non-compliance sheet in the case « Non-compliance sheet number ».
- Fill in the array, chapter 8, named « Non-compliance register ».
- Fill in the non-compliance sheet (see annex II)
- As corrective action, indicate redo action and the test number.
- Carry on the corrective action.
- Redo the test and fill the array, named « Non-compliance register ».



**7 FINAL RECEPTION :**

Final reception status :

**Acceptable**

**Non Acceptable**

Company	Function	Name	Date	Signature
NOROIT				
ESA / UAB				

**Comments :**



## 8 NON-COMPLIANCE REGISTER

The following table summarizes the non-conformities of this module.  
Critical non conformities must be resolved before starting the dynamic SAT.

Number of the non-compliance sheet	Number of the protocol section	Signature and date	Grade (Please circle the corresponding criteria)	Solution : date	Solution : Signature
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		

<b>TEST 1: Control of the attached documentation:</b>		
Re-test : <input type="checkbox"/> Yes <input type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Check the supplier documentation and ensure that the content is satisfactory, for optimal operation and easy maintenance.		
<b>PRE REQUIRED</b>		
N/A		

DOCUMENTS AUDITED	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
User manual	Available and without reserve			
Parts list (in the user manual)	Available and without reserve			
General diagram	Available and without reserve			
Electrical diagrams	Available and without reserve			
Phase angle controllers datasheet	Available and without reserve			
Fans data sheet	Available and without reserve			
Anemometers data sheet	Available and without reserve			
Pressure sensors data sheet	Available and without reserve			
Humidity/temperature sensors data sheet	Available and without reserve			
"CE" certificate. (in the user manual)	Available and without reserve			

<b><u>Comments :</u></b>				
<b>TEST STATUS</b>				
<input type="checkbox"/> <b>ACCORDANCE</b>			<input type="checkbox"/> <b>NO ACCORDANCE</b>	
			See sheet(s) of non-compliance number :	
	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :		NOROIT		
check by :		ESA / UAB		

\* C = Compliance / NC = Non Compliance

<b>TEST 2 : Control of the components an conformity to the specifications</b>		
Re-test : <input type="checkbox"/> Yes <input type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Check that each component is available.		
<b>PRE REQUIRED</b>		
N/A		

COMPONENT AUDITED	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
External dimensions length x width x height :	Conformity of dimension : 2m36 x 1m10 x 3m			
"CE" manufacturer label.	Available and without reserve			
HEPA filters ( Quantity : 12 )	Available and without reserve			
Prefilters ( Quantity : 8 )	Available and without reserve			
Fans ( Quantity : 6 )	Available and without reserve			
Valves ( Quantity : 6 )	Available and without reserve			
Humidity/temperature sensors ( Quantity : 2 )	Available and without reserve			
Pressure sensors ( Quantity : 4 )	Available and without reserve			
Airflow sensors ( Quantity : 2 )	Available and without reserve			
Connections for sterilizing agent ( Quantity : 4 )	Available and without reserve			
Sterilizing agent exhausts ( Quantity : 2 )	Available and without reserve			
Electrical compartments ( Quantity : 2 )	Available and without reserve			
Control compartment ( Quantity : 1 )	Available and without reserve			
Control panel ( Quantity : 1 )	Available and without reserve			
Colorsafe systems ( Quantity : 2 )	Available and without reserve			

<b><u>Comments :</u></b>				
<b>TEST STATUS</b>				
<input type="checkbox"/> <b>ACCORDANCE</b>			<input type="checkbox"/> <b>NO ACCORDANCE</b>	
			See sheet(s) of non-compliance number :	
	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :		NOROIT		
check by :		ESA / UAB		

\* C = Compliance / NC = Non Compliance

<b>TEST 3 : Control of the keyboard.</b>		
Re-test : <input type="checkbox"/> Yes <input type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Check that the keyboard fulfils the manual description.		
<b>PRE REQUIRED</b>		
N/A		

VERIFICATION	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Electronic key. ( Quantity : 2 )	Available			
Electronic key (female connector)	Available			
Up table button.	Available			
Down table button.	Available			
Lift table's control panel up table button.	Available			
Lift table's control panel down table button.	Available			
Lift table's control panel emergency stop button.	Available			
Input chamber's pressure display. (up)	Available			
Input chamber's pressure status leds. (up)	Available			
Input chamber's pressure setting knob. (up)	Available			
Input chamber's pressure "on/off" switch. (up)	Available			
Manipulation isolator's airflow display. (up)	Available			
Manipulation isolator's airflow status leds. (up)	Available			
Manipulation isolator's airflow setting knob. (up)	Available			
Manipulation isolator's airflow "on/off" switch. (up)	Available			
Manipulation isolator's pressure display. (up)	Available			
Manipulation isolator's pressure status leds. (up)	Available			

Manipulation isolator's pressure setting knob. (up)	Available			
Manipulation isolator's pressure "on/off" switch. (up)	Available			
Manipulation isolator's hygrometry display. (up)	Available			
Manipulation isolator's hygrometry status leds. (up)	Available			
Manipulation isolator's temperature display. (up)	Available			
Manipulation isolator's temperature status leds. (up)	Available			
Input chamber's pressure display. (down)	Available			
Input chamber's pressure status leds. (down)	Available			
Input chamber's pressure setting knob. (down)	Available			
Input chamber's pressure "on/off" switch. (down)	Available			
Manipulation isolator's airflow display. (down)	Available			
Manipulation isolator's airflow status leds. (down)	Available			
Manipulation isolator's airflow setting knob. (down)	Available			
Manipulation isolator's airflow "on/off" switch. (down)	Available			
Manipulation isolator's pressure display. (down)	Available			
Manipulation isolator's pressure status leds. (down)	Available			
Manipulation isolator's pressure setting knob. (down)	Available			
Manipulation isolator's pressure "on/off" switch. (down)	Available			
Manipulation isolator's hygrometry display. (down)	Available			
Manipulation isolator's hygrometry status leds. (down)	Available			
Manipulation isolator's temperature display. (down)	Available			
Manipulation isolator's temperature status leds. (down)	Available			



<b><u>Comments :</u></b>				
<b>TEST STATUS</b>				
<input type="checkbox"/> <b>ACCORDANCE</b>			<input type="checkbox"/> <b>NO ACCORDANCE</b>	
			See sheet(s) of non-compliance number :	
	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :		NOROIT		
check by :		ESA / UAB		

\* C = Compliance / NC = Non Compliance

<b>TEST 4 : Control of the electrical installation</b>		
Re-test : <input type="checkbox"/> Yes <input type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Check that the electrical connections match the specifications.		
<b>PRE REQUIRED</b>		
N/A		

VERIFICATION	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Electrical connections	Wall connection Three-pin plug Phase/Neutral/Earth			
Earth continuity between parts of the stand.	Continuity			

<b><u>Comments :</u></b>				
<b>TEST STATUS</b>				
<input type="checkbox"/> <b>ACCORDANCE</b>			<input type="checkbox"/> <b>NO ACCORDANCE</b>	
			See sheet(s) of non-compliance number :	
	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :		NOROIT		
check by :		ESA / UAB		

\* C = Compliance / NC = Non Compliance

<b>TEST 5 : Control of the visual aspect</b>		
Re-test : <input type="checkbox"/> Yes <input type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Check that the isolators feature no visual default.		
<b>PRE REQUIRED</b>		
N/A		

VERIFICATION	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Default inside the up isolator's chamber.	No default			
Default outside the up isolator's chamber.	No default			
Default inside the down isolator's chamber.	No default			
Default outside the down isolator's chamber.	No default			
Default inside the up transfer chamber.	No default			
Default outside the up transfer chamber.	No default			
Default inside the down transfer chamber.	No default			
Default outside the down transfer chamber.	No default			

<b><u>Comments :</u></b>				
<b>TEST STATUS</b>				
<input type="checkbox"/> <b>ACCORDANCE</b>			<input type="checkbox"/> <b>NO ACCORDANCE</b>	
			See sheet(s) of non-compliance number :	
	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :		NOROIT		
check by :		ESA / UAB		

\* C = Compliance / NC = Non Compliance

### 9 Results and observations summary

<b>Tests result</b>		
<b>TEST 1</b>	<input type="checkbox"/> <b>CONFORM</b> <input type="checkbox"/> <b>NON CONFORM</b>	See non-compliance sheet number :
<b>TEST 2</b>	<input type="checkbox"/> <b>CONFORM</b> <input type="checkbox"/> <b>NON CONFORM</b>	See non-compliance sheet number :
<b>TEST 3</b>	<input type="checkbox"/> <b>CONFORM</b> <input type="checkbox"/> <b>NON CONFORM</b>	See non-compliance sheet number :
<b>TEST 4</b>	<input type="checkbox"/> <b>CONFORM</b> <input type="checkbox"/> <b>NON CONFORM</b>	See non-compliance sheet number :
<b>TEST 5</b>	<input type="checkbox"/> <b>CONFORM</b> <input type="checkbox"/> <b>NON CONFORM</b>	See non-compliance sheet number :

**Comments :**



**Synthesis approval :**

Company	Function	Name	Date	Signature
NOROIT				
ESA / UAB				





**10 ADDENDUM :**

**ADDENDUM I**                      Documentation attached

**ADDENDUM II**                Non-compliance static SAT report

<b>ADDENDUM I : DOCUMENTATION ATTACHED</b>	<b>Pages number</b>
Fans documentation	2
Phase angle controllers documentation	2
Airflow sensors documentation	4
Hygrometry and temperature sensors documentation	4
Pressure sensors documentation	2

<b>ADDENDUM II : Non-compliance static SAT report</b>		
Module / System : Isolator	Description : .....	
	Report number : .....	
Reference protocol number : .....		
<b>1. Non-compliance description :</b>		
.....		
.....		
Noticed by :		
.....	.....	.....
Name	Signature	Date
<b>2. Non-compliance classification (tick the appropriate box) :</b>		
Critical non-compliance:	Non-critical non-compliance:	
Additional document for classification:		
.....		
Classified by :		
.....	.....	.....
Name / Department	Signature	Date
.....	.....	.....
Name / Department	Signature	Date
<b>3. Corrective action :</b>		
.....		
.....		
Description of the tests performed :		
.....		
Performed by :		
.....	.....	.....
Name	Signature	Date
Approved by :		
.....	.....	.....
Name / Department	Signature	Date

<b>ADDENDUM II : Non-compliance static SAT report</b>		
Module / System : Isolator	Description : .....	
	Report number : .....	
Reference protocol number : .....		
<b>4. Non-compliance description :</b>		
.....		
.....		
Noticed by :		
.....	.....	.....
Name	Signature	Date
<b>5. Non-compliance classification (tick the appropriate box) :</b>		
Critical non-compliance:	Non-critical non-compliance:	
Additional document for classification:		
.....		
Classified by :		
.....	.....	.....
Name / Department	Signature	Date
.....	.....	.....
Name / Department	Signature	Date
<b>6. Corrective action :</b>		
.....		
.....		
Description of the tests performed :		
.....		
Performed by :		
.....	.....	.....
Name	Signature	Date
Approved by :		
.....	.....	.....
Name / Department	Signature	Date



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**SAT PROTOCOL**  
**Operational Qualification**  
**ISOLATORS ESA BARCELONA**

Index	Description	Editing	Date	Signature
1	Creation	Julien VICTOR	07/15/09	

Approval of protocol :

Company	Function	Name	Date	Signature
ESA / UAB				

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TEST 5 Control of the pressure .....	18
TEST 6 Control of the airflow .....	20
TEST 7 Control of the temperature .....	22
TEST 8 Control of the hygrometry .....	24
9 Results and observations summary .....	26
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**1 PURPOSE: Isolator dynamic control,**  
**Serial number :** 20090702000.  
**Localisation :** Barcelona.

## **2 EQUIPMENT DESCRIPTION :**

Equipment :  
Isolator ESA Barcelona type.

### **Generality :**

The I-BOX isolators are rigid enclosures for an optimal containment of animals. I-BOX isolators are the best solutions to keep the animals in defined sanitary conditions. This isolators ensure total protection of the user, the manipulation and the environment, by means of :

- Absolute tightness of the chamber.
- Positive or negative pressure inside the chamber.
- High efficiency filtering (99.99% for 0,3 µm particles)
- Physical barrier (fiberglass body and gloves) between the user and potentially dangerous handled materials.

It also permits operation in a sterile environment.

The performance of this type of equipment depends not only on the instrument itself but also upon the following parameters:

- The user: Use of isolators must be reserved for qualified personnel having received suitable training.
- Servicing: the filters efficiency and the air cleanness measurement must be checked regularly.

### **Characteristics :**

- External dimensions : length x width x height : 2m36 x 1m10 x 3m.
- Construction : Stainless steel 316L.

### **Equipments :**

2 units of 4 glove isolators. They are located one upon the other.

- Each isolator has a transfer chamber.
- The pressure is created by fans.
- Anemometers control the airflow.
- Sensors measure temperature, hygrometry and pressure.
- Each air intake features a pre-filter.
- HEPA filter.
- 2 control panels, located :
  - On a console, next to the isolators.
  - On a lift table console, next to the isolators.

The isolators control panel features :

- Temperature, hygrometry, pressure and airflow displays. One for each measurement and for each isolator.
- A green LED, which indicates the correct value, for each variable and each isolator.
- A red LED, which indicates the value in default, for each variable and each isolator.
- Two trimmers control the airflow for each isolator and another two control the pressure for each isolator.
- "on/off" switches start / stop pressure and airflow fan. One for each variable and for each isolator.
- An electronic key, switches on / off the unit.

### 3 SIGNATURES ARRAY:

Company	Function	Name	Date	Signature
NOROIT				
ESA / UAB				

### 4 DYNAMIC SAT TESTS EXECUTION

The execution of the dynamic SAT tests is performed on the site of the :

Departament de Enginyeria Química  
Escola Tècnica Superior de Enginyeria (ETSE)  
Universitat Autònoma de Barcelona  
Campus de Bellaterra, Barcelona.

They are performed by Noroit and controlled by Ms. Munganga.

### 5 DYNAMIC TESTS LIST

- Test 1 : Control of the keyboard functions.
- Test 2 : Control of the colorsafe functionality.
- Test 3 : Control of the lift table.
- Test 4 : Control of the air cleanliness classification : ISO 5 – Class 100.
- Test 5 : Control of the pressure.
- Test 6 : Control of the airflow.
- Test 7 : Control of the temperature measurement.
- Test 8 : Control of the hygrometry measurement.

### 6 NON-COMPLIANCE HANDLING

In case of non compliance, for a test :

- In the array, chapter 9, « Results and observations summary », indicate the number of the non-compliance sheet in the case « Non-compliance sheet number ».
- Fill in the array, chapter 8, named « Non-compliance register ».
- Fill in the non-compliance sheet (see annex II)
- As corrective action, indicate redo action and the test number.
- Carry on the corrective action.
- Redo the test and fill the array, named « Non-compliance register ».





**7 FINAL RECEPTION :**

Final reception status :

**Acceptable**

**Non Acceptable**

Company	Function	Name	Date	Signature
NOROIT				
ESA / UAB				

**Comments :**

**8 NON-COMPLIANCE REGISTER :**

The following table summarizes the non-conformities of this module.  
Critical non conformities must be resolved before operating the unit.

Number of the non-compliance sheet	Number of the protocol section	Signature and date	Grade (Please circle the corresponding criteria)	Solution : date	Solution : Signature
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		

<b>TEST 1: Control of the keyboard functions :</b>		
Re-test : <input type="checkbox"/> Yes <input type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Check the correct functioning of the keyboard and associated functions.		
<b>PRE REQUIRED</b>		
Electrical connection of the equipment.		

**UP isolators :**

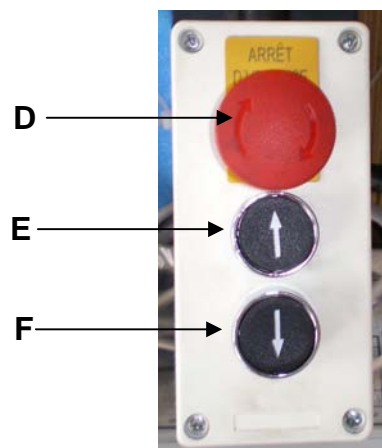
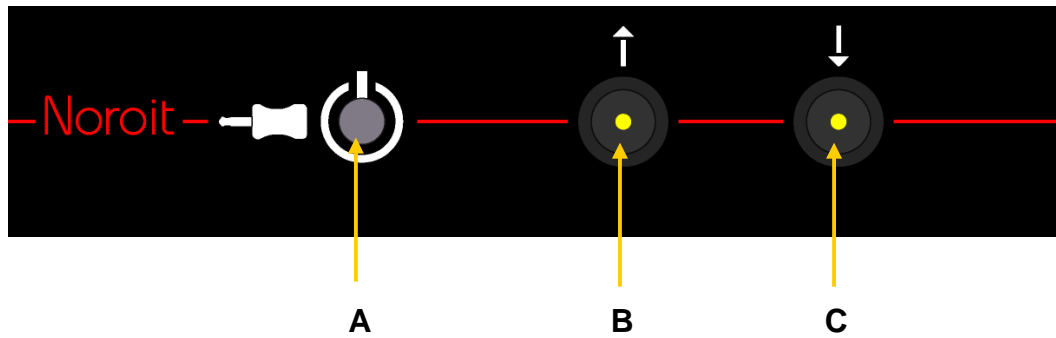
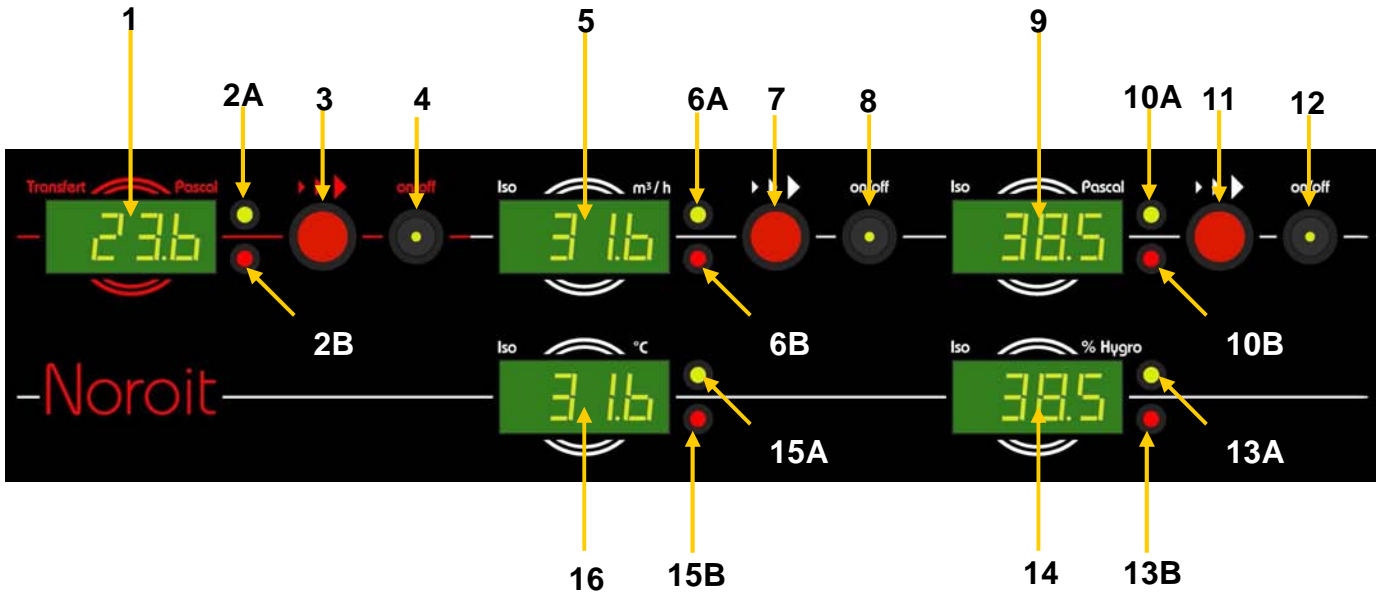
TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Insert the key in A.	The displays flash			
Press the button 4	The LED in the middle of the button flashes			
Press the button 8	The LED in the middle of the button flashes			
Press the button 12	The LED in the middle of the button flashes			
Turn the knob 3 clockwise	The pressure in the transfer chamber increases			
Turn the knob 7 clockwise	The airflow in the up isolator increases			
Turn the knob 11 clockwise	The pressure in the up isolator increases			
Increase the pressure in the transfer chamber over 70 Pa	The LED 2B flashes, after 10s delay			
Decrease the pressure in the transfer chamber under 15 Pa	The LED 2B flashes, after 10s delay			
Set the pressure in the transfer chamber between 15 and 70 Pa.	The LED 2A flashes			
Increase the airflow in the isolator over 70 meter <sup>3</sup> /h.	The LED 6B flashes, after 10s delay.			
Decrease the airflow in the isolator under 30 meter <sup>3</sup> /h	The LED 6B flashes, after 10s delay			

Set the airflow in the isolator between 30 and 70 meter <sup>3</sup> /h	The LED 6A flashes			
Increase the pressure in the isolator over 75 Pa	The LED 10B flashes, after 10s delay			
Decrease the pressure in the isolator under 25 Pa	The LED 10B flashes, after 10s delay			
Put the pressure in the isolator between 25 and 75 Pa	The LED 10A flashes			
Press the button B	The lift table goes up			
Press the button C	The lift table goes down			
Press the button E	The lift table goes up			
Press the button F	The lift table goes down			
Press the button D	Button B, C, E and F are inactive. The lift table do not move			

**DOWN isolators :**

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Press the button 4	The LED in the middle of the button flashes			
Press the button 8	The LED in the middle of the button flashes			
Press the button 12	The LED in the middle of the button flashes			
Turn the knob 3 clockwise	The pressure in the transfer chamber increases			
Turn the knob 7 clockwise	The airflow in the up isolator increases			
Turn the knob 11 clockwise	The pressure in the up isolator increases			
Increase the pressure in the transfer chamber over 70 Pa	The LED 2B flashes, after 10s delay			
Decrease the pressure in the transfer chamber under 15 Pa	The LED 2B flashes, after 10s delay			
Set the pressure in the transfer chamber between 15 and 70 Pa.	The LED 2A flashes			

Increase the airflow in the isolator over 70 meter <sup>3</sup> /h.	The LED 6B flashes, after 10s delay.			
Decrease the airflow in the isolator under 30 meter <sup>3</sup> /h	The LED 6B flashes, after 10s delay			
Set the airflow in the isolator between 30 and 70 meter <sup>3</sup> /h	The LED 6A flashes			
Increase the pressure in the isolator over 75 Pa	The LED 10B flashes, after 10s delay			
Decrease the pressure in the isolator under 25 Pa	The LED 10B flashes, after 10s delay			
Put the pressure in the isolator between 25 and 75 Pa	The LED 10A flashes			



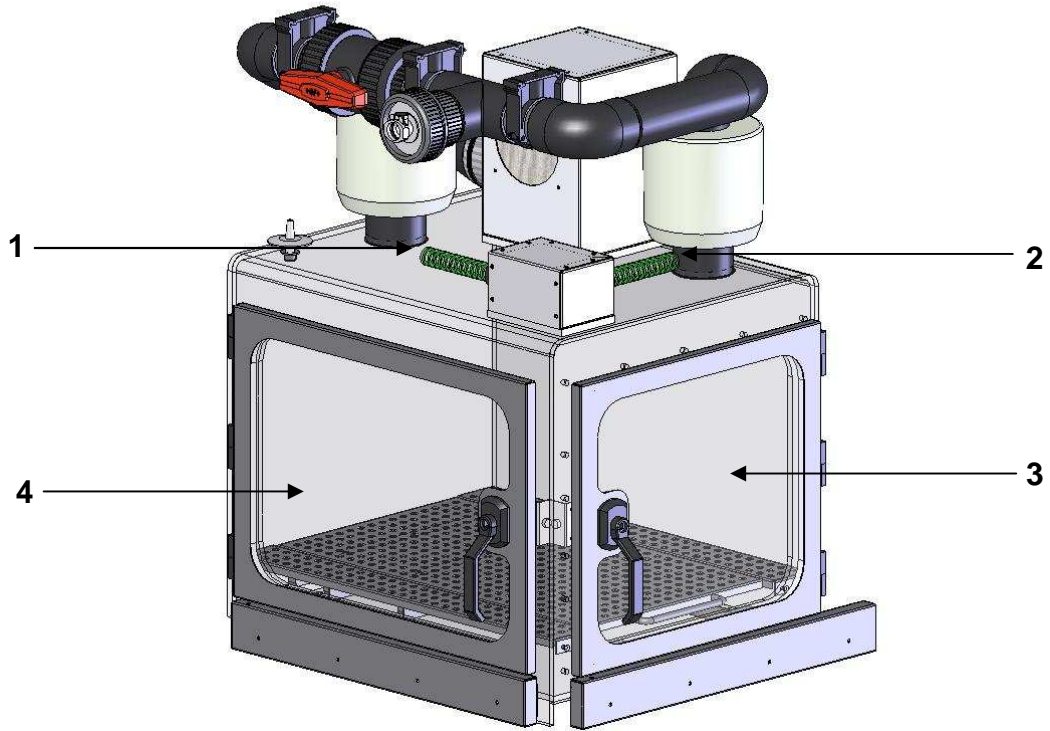
<b><u>Comments :</u></b>				
<b>TEST STATUS</b>				
<input type="checkbox"/> <b>ACCORDANCE</b>			<input type="checkbox"/> <b>NO ACCORDANCE</b>	
			See sheet(s) of non-compliance number :	
	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :		NOROIT		
check by :		ESA / UAB		

\* C = Compliance / NC = Non Compliance

<b>TEST 2 : Control of the colorsafe functionality</b>		
Re-test : <input type="checkbox"/> Yes <input type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Controls the functionality of the colorsafe system for each transfer chamber		
<b>PRE REQUIRED</b>		
Electrical connection of the equipment		

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Close the door 3 and 4	The bars 1 and 2 flash green.			
Open the door 3, door 4 remains closed.	The bars 1 flashes red and the bar 2 flashes green.			
Open the door 4, door 3 remains closed	The bars 1 flashes green and the bar 2 flashes red.			





**Comments :**

---

**TEST STATUS**

**ACCORDANCE**
                         
  **NO ACCORDANCE**

See sheet(s) of non-compliance number :

	Name	Company	Date	Signature
Tested by :		NOROIT		
check by :		ESA / UAB		

\* C = Compliance / NC = Non Compliance

<b>TEST 3 : Control of the lift table</b>		
Re-test : <input type="checkbox"/> Yes <input type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Control the sensitive border of the lift table.		
<b>PRE REQUIRED</b>		
The lift table must be correctly supplied.		

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Press the sensitive border of the lift table. Press the C button to move down the lift table	The lift table does not move			

<b><u>Comments :</u></b>				
<b>TEST STATUS</b>				
<input type="checkbox"/> <b>ACCORDANCE</b>			<input type="checkbox"/> <b>NO ACCORDANCE</b>	
			See sheet(s) of non-compliance number :	
	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :		NOROIT		
check by :		ESA / UAB		

\* C = Compliance / NC = Non Compliance

<b>TEST 4 : Control of the air cleanliness classification : ISO 5 – Class 100</b>		
Re-test : <input type="checkbox"/> Yes <input type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Check the air cleanliness : class 100 inside the isolator.		
<b>PRE REQUIRED</b>		
Isolators must be running for at least 30 minutes. Particle counter available.		

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Pre required : Install the sensor of the particle counter in the up isolator. Make the counting for one cubic feet. Print the results	Less than 100 particles of 0.3µm, per cubic feet.			
Pre required : Install the sensor of the particle counter in the down isolator. Make the counting for one cubic feet. Print the results	Less than 100 particles of 0.3µm, per cubic feet.			
Pre required : Install the sensor of the particle counter in the up transfer chamber. Make the counting for one cubic feet. Print the results	Less than 100 particles of 0.3µm, per cubic feet..			
Pre required : Install the sensor of the particle counter in the down transfer chamber. Make the counting for one cubic feet. Print the results	Less than 100 particles of 0.3µm, per cubic feet.			

Particle counter sensor installation in an isolator :  
The particle counter sensor passes through a glove finger. The sealing is ensured by cable clamps.  
The counting is performed in the transfer chamber with the communication door (door 3, see test 2) opened.

<b><u>Comments :</u></b>				
<b>TEST STATUS</b>				
<input type="checkbox"/> <b>ACCORDANCE</b>			<input type="checkbox"/> <b>NO ACCORDANCE</b>	
			See sheet(s) of non-compliance number :	
	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :		NOROIT		
check by :		ESA / UAB		

\* C = Compliance / NC = Non Compliance

<b>TEST 5 : Control of the pressure</b>		
Re-test : <input type="checkbox"/> Yes <input type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Controls the pressure displayed for each isolator and for each transfer chamber		
<b>PRE REQUIRED</b>		
Electrical connection of the equipment. Isolators must be running		

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Install the sensor in the up isolator	The pressure measured and displayed on the control panel are the same $\pm 10\%$ .			
Install the sensor in the down isolator	The pressure measured and displayed on the control panel are the same $\pm 10\%$ .			
Install the sensor in the up transfer chamber	The pressure measured and displayed on the control panel are the same $\pm 10\%$ .			
Install the sensor in the down transfer chamber	The pressure measured and displayed on the control panel are the same $\pm 10\%$ .			

Pressure sensor installation in an isolator :

The pressure sensor passes through a glove finger. The sealing is ensured by cable clamps.

For the transfer chambers, the pressure sensor is connected after the "Millipore" absolute output filter.

<b><u>Comments :</u></b>				
<b>TEST STATUS</b>				
<input type="checkbox"/> <b>ACCORDANCE</b>			<input type="checkbox"/> <b>NO ACCORDANCE</b>	
			See sheet(s) of non-compliance number :	
	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :		NOROIT		
check by :		ESA / UAB		

\* C = Compliance / NC = Non Compliance

<b>TEST 6 : Control of the airflow</b>		
Re-test : <input type="checkbox"/> Yes <input type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Controls the airflow displayed for each isolator		
<b>PRE REQUIRED</b>		
Electrical connection of the equipment Isolators must be running		

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Install the sensor at the exhaust of the up isolator	The airflow measured and displayed on the control panel are the same $\pm 10\%$ .			
Install the sensor at the exhaust of the down isolator	The airflow measured and displayed on the control panel are the same $\pm 10\%$ .			

Airflow sensor installation :  
The airflow sensor is installed at the exhaust of the isolator's ventilation network.



<b><u>Comments :</u></b>				
<b>TEST STATUS</b>				
<input type="checkbox"/> <b>ACCORDANCE</b>			<input type="checkbox"/> <b>NO ACCORDANCE</b>	
			See sheet(s) of non-compliance number :	
	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :		NOROIT		
check by :		ESA / UAB		

\* C = Compliance / NC = Non Compliance

<b>TEST 7 : Control of the temperature</b>		
Re-test : <input type="checkbox"/> Yes <input type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Controls the temperature displayed for each isolator		
<b>PRE REQUIRED</b>		
Electrical connection of the equipment Isolators must be running		

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Install the sensor in the up isolator	The temperature measured and displayed on the control panel are the same $\pm 10\%$ .			
Install the sensor in the down isolator	The temperature measured and displayed on the control panel are the same $\pm 10\%$ .			

Temperature sensor installation :

The temperature sensor passes through a glove finger. The sealing is ensured by cable clamps.

The temperature is measured close to the isolator's probe.

<b><u>Comments :</u></b>				
<b>TEST STATUS</b>				
<input type="checkbox"/> <b>ACCORDANCE</b>			<input type="checkbox"/> <b>NO ACCORDANCE</b>	
			See sheet(s) of non-compliance number :	
	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :		NOROIT		
check by :		ESA / UAB		

\* C = Compliance / NC = Non Compliance

<b>TEST 8 : Control of the hygrometry</b>		
Re-test : <input type="checkbox"/> Yes <input type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Controls the hygrometry displayed for each isolator		
<b>PRE REQUIRED</b>		
Electrical connection of the equipment Isolators must be running		

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Install the sensor in the up isolator	The hygrometry rate measured and displayed on the control panel are the same $\pm 20\%$ .			
Install the sensor in the down isolator	The hygrometry rate measured and displayed on the control panel are the same $\pm 20\%$ .			

Hygrometry sensor installation :

The hygrometry sensor passes through a glove finger. The sealing is ensured by cable clamps.  
The hygrometry is measured close to the isolator's probe.

<b><u>Comments :</u></b>				
<b>TEST STATUS</b>				
<input type="checkbox"/> <b>ACCORDANCE</b>			<input type="checkbox"/> <b>NO ACCORDANCE</b>	
			See sheet(s) of non-compliance number :	
	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :		NOROIT		
check by :		ESA / UAB		

\* C = Compliance / NC = Non Compliance





**Synthesis approval :**

Company	Function	Name	Date	Signature
NOROIT				
ESA / UAB				



**10 ADDENDUM :**

Addendum I

Documentation attached

Addendum II

Non-compliance dynamic SAT report





<b>Addendum I : DOCUMENTATION ATTACHED</b>	<b>Page number</b>

<b>ANNEXE II : Non-compliance dynamic SAT report</b>		
Module / System : Isolator	Description : .....	
	Report number : .....	
Reference protocol number : .....		
<b>1. Non-compliance description :</b>		
.....		
.....		
Noticed by :		
.....	.....	.....
Name	Signature	Date
<b>2. Non-compliance classification (tick the appropriate box) :</b>		
Critical non-compliance:	Non-critical non-compliance:	
Additional document for classification:		
.....		
Classified by :		
.....	.....	.....
Name / Department	Signature	Date
.....	.....	.....
Name / Department	Signature	Date
<b>3. Corrective action :</b>		
.....		
.....		
Description of the tests performed :		
.....		
Performed by :		
.....	.....	.....
Name	Signature	Date
Approved by :		
.....	.....	.....
Name / Department	Signature	Date

<b>ANNEXE II : Non-compliance dynamic SAT report</b>		
Module / System : Isolator	Description : .....	
	Report number : .....	
Reference protocol number : .....		
<b>4. Non-compliance description :</b>		
.....		
.....		
Noticed by :		
.....	.....	.....
Name	Signature	Date
<b>5. Non-compliance classification (tick the appropriate box) :</b>		
Critical non-compliance:	Non-critical non-compliance:	
Additional document for classification:		
.....		
Classified by :		
.....	.....	.....
Name / Department	Signature	Date
.....	.....	.....
Name / Department	Signature	Date
<b>6. Corrective action :</b>		
.....		
.....		
Description of the tests performed :		
.....		
Performed by :		
.....	.....	.....
Name	Signature	Date
Approved by :		
.....	.....	.....
Name / Department	Signature	Date



The breath of protection

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TECHNICAL SPECIFICATION      50032 A

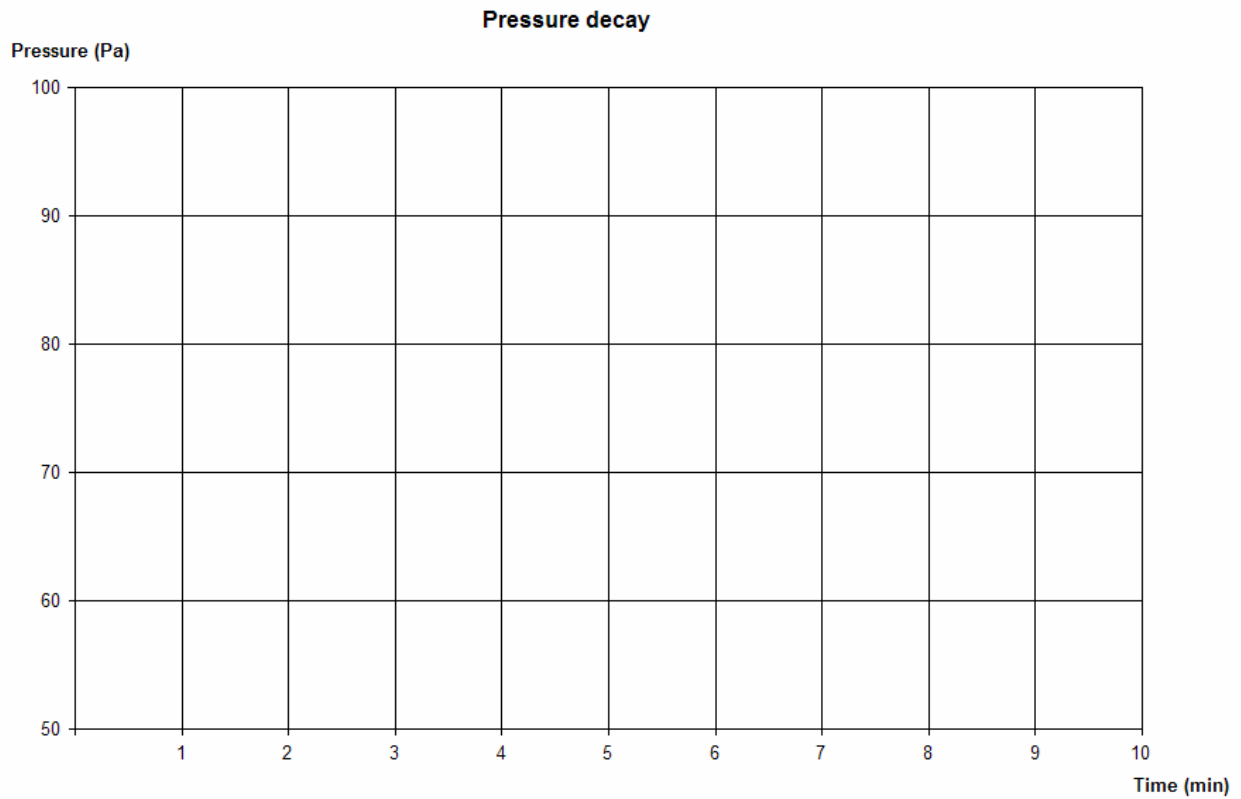
LEAK TEST :  
PRESSURE DECAY PER TIME

**DESCRIPTION :**

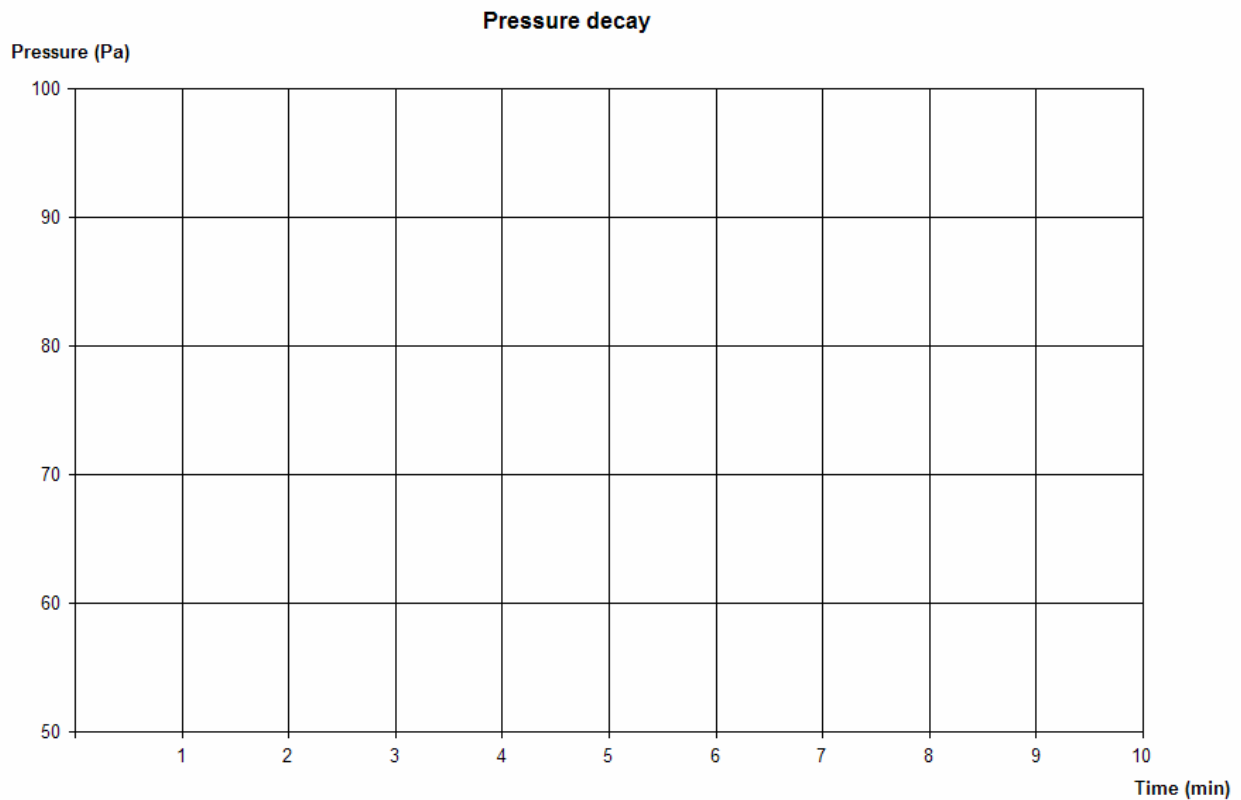
<b>LEAK TEST : PRESSURE DECAY PER TIME.</b>
Controls the tightness of the isolator
<b>PRE REQUIRED</b>
Electrical connection of the equipment. Isolators must be running.

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
1 Set the positive pressure inside the up isolator to 100 Pa. To achieve this, use the airflow knob only. The pressure fan must be switched off.	100 Pa $\pm$ 10% is displayed on the control panel.			
2 The isolator must be left running for at least 5 minutes, time enough for the pressure to stabilize.	100 Pa $\pm$ 10% is displayed on the control panel.			
3 Set the 2 position valves, normally used for sterilization, to the closed position. This procedure will totally isolate the up isolator from the ventilation network.	--			
4 Switch off the fan.	--			
5 Wait for 10 minutes. Note the pressure value displayed, every minute.	After 10 minutes, the displayed value must not drop below 75 Pa			
6 Same procedure for the down isolator.				

**Graph -- UP isolator :**



**Graph -- DOWN isolator :**



<b>Comments :</b>				
<b>TEST STATUS :</b>				
<input type="checkbox"/> <b>ACCORDANCE</b> <span style="margin-left: 200px;"><input type="checkbox"/> <b>NO ACCORDANCE</b></span>				
:				
	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :		NOROIT		
check by :		ESA / UAB		

## 9. SAT AS-RUN PROCEDURES

- **Installation qualification**
- **Operation qualification**
- **Annex to OQ Test4: Particle count datalogging (23.07.09 and 10.12.09)**
- **Leak Test (December 2010)**
- **Leak Test (March 2011)**
- **Particle count (march 2011)**
- **Annex to particle count test: Particle count datalogging (23.07.09 and 10.12.09)**
- **Annex to particle count test: Particle counter certificate**





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**SAT PROTOCOL**  
**Installation qualification**  
**ISOLATORS ESA BARCELONA**

Index	Description	Editing	Date	Signature
1	Creation	Victor JULIEN	07/06/09	

**Approval of protocol**

Company	Function	Name	Date	Signature
ESA / UAB	MAINTENANCE TECHNICIAN	Raül NOYANO	22/07/09	

## Summary

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2 Equipment description .....	3
3 Signatures array .....	4
4 Static SAT tests execution .....	4
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7 Final reception .....	5
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TEST 2 Controls the components and the compliance with specifications.....	9
TEST 3 Controls the keyboard.....	11
TEST 4 Controls the electrical installation .....	14
TEST 5 Controls the visual aspect .....	16
9 Results and observations summary .....	18
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<b>ADDENDUM I : DOCUMENTATION ATTACHED .....</b>	<b>21</b>
<b>ADDENDUM II : NON-COMPLIANCE STATIC SAT REPORT .....</b>	<b>22</b>

**1 PURPOSE: Isolator static control,**  
**Serial number : 20090702000.**  
**Localisation : Barcelona.**

**2 EQUIPMENT DESCRIPTION :**

Equipment :  
Isolator ESA Barcelona type.

**Overall description :**

The I-BOX isolators are rigid enclosures for an optimal containment of animals. I-BOX isolators are the best solutions to keep the animals in defined sanitary conditions. This isolators ensure total protection of the user, the manipulation and the environment, by means of :

- Absolute tightness of the chamber.
- Positive pressure inside the chamber.
- High efficiency filtering (99.99% for 0,3 µm particles)
- Physical barrier (fiberglass body and gloves) between the user and potentially dangerous handled materials.

It also enables operation in a sterile environment.

The performance of this type of equipment depends not only on the instrument itself but also upon the following parameters:

- The user: Use of isolators must be reserved for qualified personnel having received suitable training.
- Servicing: the filters efficiency and the air cleanness measurement must be checked regularly and at preferably, once a year.

**Characteristics :**

- External dimensions : length x width x height : 2m36 x 1m10 x 3m.
- Construction : Stainless steel 316 L.

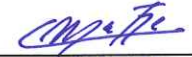

**Equipments :**

- 2 units of 4 glove isolators. They are located one upon the other.
- Each isolator has a transfer chamber.
- The pressure is created by fans.
- Anemometers control the airflow.
- Sensors measure temperature, hygrometry and pressure.
- Each air intake features a pre-filter.
- HEPA filter.
- 2 control panels, located :
  - On a console, next to the isolators.
  - On a lift table console, next to the isolators.

The isolators control panel features :

- Temperature, hygrometry, pressure and airflow displays. One for each measurement and for each isolator.
- A green LED, which indicates the correct value, for each variable and each isolator.
- A red LED, which indicates the value in default, for each variable and each isolator.
- Two trimmers control the airflow for each isolator and another two control the pressure for each isolator.
- "on/off" switches start / stop pressure and airflow fan. One for each variable and for each isolator.
- An electronic key, switches on / off the unit.

### 3 SIGNATURES ARRAY :

Company	Function	Name	Date	Signature
NOROIT	Chairman.	Gilles RAHE	22/07/09	
ESA / UAB	TECHNICIAN MSINI.	Raul MOYANO	22/07/09	

### 4 STATIC SAT TESTS EXECUTION

The execution of the static SAT tests is performed on the site of the:  
 Departament de Enginyeria Química  
 Escola Tècnica Superior de Enginyeria (ETSE)  
 Universitat Autònoma de Barcelona  
 Campus de Bellaterra, Barcelona.

They are performed by Noroit and controlled by Ms. Munganga / Mr. Moyano.

### 5 STATIC TESTS LIST

- Test 1 : Controls the attached documentation.
- Test 2 : Controls the components and the compliance with specifications.
- Test 3 : Controls the keyboard.
- Test 4 : Controls the electrical installation.
- Test 5 : Controls that there is no visual default.

### 6 NON-COMPLIANCE HANDLING

In case of non compliance, for a test :

- In the array, chapter 9, « Results and observations summary », indicate the number of the non-compliance sheet in the case « Non-compliance sheet number ».
- Fill in the array, chapter 8, named « Non-compliance register ».
- Fill in the non-compliance sheet (see annex II)
- As corrective action, indicate redo action and the test number.
- Carry on the corrective action.
- Redo the test and fill the array, named « Non-compliance register ».





**7 FINAL RECEPTION :**

Final reception status :

**Acceptable**

**Non Acceptable**

Company	Function	Name	Date	Signature
NOROIT	Chairman	Gilles NAHE	22/07/03	
ESA / UAB	TECHNICIAN MAINT.	Raul MOZANO	22/07/09	











Comments :

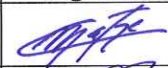

### 8 NON-COMPLIANCE REGISTER

The following table summarizes the non-conformities of this module.  
Critical non conformities must be resolved before starting the dynamic SAT.

Number of the non-compliance sheet	Number of the protocol section	Signature and date	Grade (Please circle the corresponding criteria)	Solution : date	Solution : Signature
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		

<b>TEST 1: Control of the attached documentation:</b>		
Re-test : <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Check the supplier documentation and ensure that the content is satisfactory, for optimal operation and easy maintenance.		
<b>PRE REQUIRED</b>		
N/A		
















DOCUMENTS AUDITED	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
User manual	Available and without reserve	OK		22/07/09 
Parts list (in the user manual)	Available and without reserve	OK		
General diagram	Available and without reserve	OK		
Electrical diagrams	Available and without reserve	OK		
Phase angle controllers datasheet	Available and without reserve	OK		
Fans data sheet	Available and without reserve	OK		
Anemometers data sheet	Available and without reserve	OK		
Pressure sensors data sheet	Available and without reserve	OK		
Humidity/temperature sensors data sheet	Available and without reserve	OK		
"CE" certificate. (in the user manual)	Available and without reserve	OK		

<b>Comments :</b>				
<b>TEST STATUS</b>				
<input checked="" type="checkbox"/> <b>ACCORDANCE</b>			<input type="checkbox"/> <b>NO ACCORDANCE</b>	
			See sheet(s) of non-compliance number :	
	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :	<i>Gilles MAHE</i>	NOROIT	<i>22/07/09</i>	
check by :	<i>Raul Noyano</i>	ESA / UAB	<i>22/07/09</i>	

\* C = Compliance / NC = Non Compliance



<b>TEST 2 : Control of the components an conformity to the specifications</b>		
Re-test : <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Check that each component is available.		
<b>PRE REQUIRED</b>		
N/A		

COMPONENT AUDITED	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
External dimensions length x width x height :	Conformity of dimension : 2m36 x 1m10 x 3m	OK		22/07/09 
"CE" manufacturer label.	Available and without reserve	Missing	To be send by post	
HEPA filters ( Quantity : 12 )	Available and without reserve	OK		
Prefilters ( Quantity : 8 )	Available and without reserve	OK		
Fans ( Quantity : 6 )	Available and without reserve	OK		
Valves ( Quantity : 6 )	Available and without reserve	OK		
Humidity/temperature sensors ( Quantity : 2 )	Available and without reserve	OK		
Pressure sensors ( Quantity : 4 )	Available and without reserve	OK		
Airflow sensors ( Quantity : 2 )	Available and without reserve	OK		
Connections for sterilizing agent ( Quantity : 4 )	Available and without reserve	OK		
Sterilizing agent exhausts ( Quantity : 2 )	Available and without reserve	OK		
Electrical compartments ( Quantity : 2 )	Available and without reserve	OK		
Control compartment ( Quantity : 1 )	Available and without reserve	OK		
Control panel ( Quantity : 1 )	Available and without reserve	OK		
Colorsafe systems ( Quantity : 2 )	Available and without reserve	OK		

**Comments :**

"CE" Manufacturer label is missing. To be send by post, in August.

CE label is delivery and accepted.

Emmanuel Pein 12.03.10

*[Signature]* 12/03/10.

**TEST STATUS**

**ACCORDANCE**

**NO ACCORDANCE**

See sheet(s) of non-compliance number :

	Name	Company	Date	Signature
Tested by :	Gilles PAHE	NOROIT	22/07/09	<i>[Signature]</i>
check by :	Raul POYANO	ESA / UAB	22/07/09	<i>[Signature]</i>

\* C = Compliance / NC = Non Compliance

<b>TEST 3 : Control of the keyboard.</b>		
Re-test : <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Check that the keyboard fulfils the manual description.		
<b>PRE REQUIRED</b>		
N/A		

VERIFICATION	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Electronic key. ( Quantity : 2 )	Available	OK		22/07/09
Electronic key (female connector)	Available	OK		
Up table button.	Available	OK		
Down table button.	Available	OK		
Lift table's control panel up table button.	Available	OK		
Lift table's control panel down table button.	Available	OK		
Lift table's control panel emergency stop button.	Available	OK		
Input chamber's pressure display. (up)	Available	OK		
Input chamber's pressure status leds. (up)	Available	OK		
Input chamber's pressure setting knob. (up)	Available	OK		
Input chamber's pressure "on/off" switch. (up)	Available	OK		
Manipulation isolator's airflow display. (up)	Available	OK		
Manipulation isolator's airflow status leds. (up)	Available			
Manipulation isolator's airflow setting knob. (up)	Available			
Manipulation isolator's airflow "on/off" switch. (up)	Available			
Manipulation isolator's pressure display. (up)	Available			
Manipulation isolator's pressure status leds. (up)	Available			



Manipulation isolator's pressure setting knob. (up)	Available	OK		22/07/09
Manipulation isolator's pressure "on/off" switch. (up)	Available			
Manipulation isolator's hygrometry display. (up)	Available			
Manipulation isolator's hygrometry status leds. (up)	Available			
Manipulation isolator's temperature display. (up)	Available			
Manipulation isolator's temperature status leds. (up)	Available			
Input chamber's pressure display. (down)	Available			
Input chamber's pressure status leds. (down)	Available			
Input chamber's pressure setting knob. (down)	Available			
Input chamber's pressure "on/off" switch. (down)	Available			
Manipulation isolator's airflow display. (down)	Available			
Manipulation isolator's airflow status leds. (down)	Available			
Manipulation isolator's airflow setting knob. (down)	Available			
Manipulation isolator's airflow "on/off" switch. (down)	Available			
Manipulation isolator's pressure display. (down)	Available			
Manipulation isolator's pressure status leds. (down)	Available			
Manipulation isolator's pressure setting knob. (down)	Available			
Manipulation isolator's pressure "on/off" switch. (down)	Available			
Manipulation isolator's hygrometry display. (down)	Available			
Manipulation isolator's hygrometry status leds. (down)	Available			
Manipulation isolator's temperature display. (down)	Available			
Manipulation isolator's temperature status leds. (down)	Available	OK		

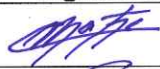

**Comments :**

**TEST STATUS**

**ACCORDANCE**

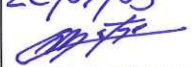

**NO ACCORDANCE**

See sheet(s) of non-compliance number :

	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :	Gilles MAHE	NOROIT	22/07/09	
check by :	Raul MOYANO	ESA / UAB	22/07/09	

\* C = Compliance / NC = Non Compliance

<b>TEST 4 : Control of the electrical installation</b>		
Re-test : <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Check that the electrical connections match the specifications.		
<b>PRE REQUIRED</b>		
N/A		

VERIFICATION	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Electrical connections	Wall connection Three-pin plug Phase/Neutral/Earth	OK		22/07/09 
Earth continuity between parts of the stand.	Continuity	OK		



**Comments :**

**TEST STATUS**

**ACCORDANCE**









**NO ACCORDANCE**

See sheet(s) of non-compliance number :

	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :	Gilles MAHE	NOROIT	22/07/09	
check by :	Raul ROYANO	ESA / UAB	22/07/09	

\* C = Compliance / NC = Non Compliance

<b>TEST 5 : Control of the visual aspect</b>		
Re-test : <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Check that the isolators feature no visual default.		
<b>PRE REQUIRED</b>		
N/A		

VERIFICATION	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Default inside the up isolator's chamber.	No default	OK		22/07/09 
Default outside the up isolator's chamber.	No default	OK		
Default inside the down isolator's chamber.	No default	OK		
Default outside the down isolator's chamber.	No default	Small default.		
Default inside the up transfer chamber.	No default	OK		
Default outside the up transfer chamber.	No default	OK		
Default inside the down transfer chamber.	No default	OK		
Default outside the down transfer chamber.	No default	OK		



**Comments :**

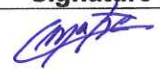

Small default outside the down isolator's chamber.  
Not critical.  
Created while moving the equipment.

**TEST STATUS**

**ACCORDANCE**

**NO ACCORDANCE**

See sheet(s) of non-compliance number :

	Name	Company	Date	Signature
Tested by :	Gilles MAHE	NOROIT	22/07/09	
check by :	Raul MOYANO	ESA / UAB	22/07/09	

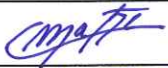

\* C = Compliance / NC = Non Compliance

### 9 Results and observations summary

<b>Tests result</b>		
<b>TEST 1</b>	<input checked="" type="checkbox"/> <b>CONFORM</b> <input type="checkbox"/> <b>NON CONFORM</b>	See non-compliance sheet number :
<b>TEST 2</b>	<input checked="" type="checkbox"/> <b>CONFORM</b> <input type="checkbox"/> <b>NON CONFORM</b>	See non-compliance sheet number :
<b>TEST 3</b>	<input checked="" type="checkbox"/> <b>CONFORM</b> <input type="checkbox"/> <b>NON CONFORM</b>	See non-compliance sheet number :
<b>TEST 4</b>	<input checked="" type="checkbox"/> <b>CONFORM</b> <input type="checkbox"/> <b>NON CONFORM</b>	See non-compliance sheet number :
<b>TEST 5</b>	<input checked="" type="checkbox"/> <b>CONFORM</b> <input type="checkbox"/> <b>NON CONFORM</b>	See non-compliance sheet number :

**Comments :**

**Synthesis approval :**

Company	Function	Name	Date	Signature
NOROIT	Chairman	Gilles MAHE	22/07/09	
ESA / UAB	TECHNICIAN MAINT.	Raul POYANO	22/07/09	



**10 ADDENDUM :**

- ADDENDUM I**                      Documentation attached
- ADDENDUM II**                Non-compliance static SAT report

<b>ADDENDUM I : DOCUMENTATION ATTACHED</b>	<b>Pages number</b>
Fans documentation	2
Phase angle controllers documentation	2
Airflow sensors documentation	4
Hygrometry and temperature sensors documentation	4
Pressure sensors documentation	2

**ADDENDUM II : Non-compliance static SAT report**

Module / System : Isolator

Description : .....

Report number : .....

Reference protocol number : .....

**1. Non-compliance description :**

.....  
.....

Noticed by :

.....  
Name Signature Date

**2. Non-compliance classification (tick the appropriate box) :**

Critical non-compliance:  Non-critical non-compliance:

Additional document for classification:

.....

Classified by :

.....  
Name / Department Signature Date

.....  
Name / Department Signature Date

**3. Corrective action :**

.....  
.....

Description of the tests performed :

.....

Performed by :

.....  
Name Signature Date

Approved by :

.....  
Name / Department Signature Date

**ADDENDUM II : Non-compliance static SAT report**

Module / System : Isolator

Description : .....

Report number : .....

Reference protocol number : .....

**4. Non-compliance description :**

.....  
.....

Noticed by :

.....  
Name Signature Date

**5. Non-compliance classification (tick the appropriate box) :**

Critical non-compliance:  Non-critical non-compliance:

Additional document for classification:

.....

Classified by :

.....  
Name / Department Signature Date

.....  
Name / Department Signature Date

**6. Corrective action :**

.....  
.....

Description of the tests performed :

.....

Performed by :

.....  
Name Signature Date

Approved by :

.....  
Name / Department Signature Date







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**SAT PROTOCOL**  
**Operational Qualification**  
**ISOLATORS ESA BARCELONA**

Index	Description	Editing	Date	Signature
1	Creation	Julien VICTOR	07/15/09	

Approval of protocol :

Company	Function	Name	Date	Signature
ESA / UAB	Maintenance technician	Raul NOYANO	03/07/09	



## SUMMARY

1 Purpose .....	3
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5 Dynamic tests List .....	4
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TEST 2 Control of the colorsafe functionality .....	12
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TEST 8 Control of the hygrometry .....	24
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<b>ADDENDUM II : NON-COMPLIANCE DYNAMIC SAT REPORT .....</b>	<b>30</b>

**1 PURPOSE: Isolator dynamic control,**  
**Serial number :** 20090702000.  
**Localisation :** Barcelona.

## **2 EQUIPMENT DESCRIPTION :**

Equipment :  
Isolator ESA Barcelona type.

### **Generality :**

The I-BOX isolators are rigid enclosures for an optimal containment of animals. I-BOX isolators are the best solutions to keep the animals in defined sanitary conditions. This isolators ensure total protection of the user, the manipulation and the environment, by means of :

- Absolute tightness of the chamber.
- Positive or negative pressure inside the chamber.
- High efficiency filtering (99.99% for 0,3 µm particles)
- Physical barrier (fiberglass body and gloves) between the user and potentially dangerous handled materials.

It also permits operation in a sterile environment.

The performance of this type of equipment depends not only on the instrument itself but also upon the following parameters:

- The user: Use of isolators must be reserved for qualified personnel having received suitable training.
- Servicing: the filters efficiency and the air cleanness measurement must be checked regularly.

### **Characteristics :**

- External dimensions : length x width x height : 2m36 x 1m10 x 3m.
- Construction : Stainless steel 316L.

### **Equipments :**

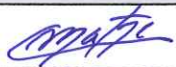


2 units of 4 glove isolators. They are located one upon the other.

- Each isolator has a transfer chamber.
- The pressure is created by fans.
- Anemometers control the airflow.
- Sensors measure temperature, hygrometry and pressure.
- Each air intake features a pre-filter.
- HEPA filter.
- 2 control panels, located :
  - On a console, next to the isolators.
  - On a lift table console, next to the isolators.

The isolators control panel features :

- Temperature, hygrometry, pressure and airflow displays. One for each measurement and for each isolator.
- A green LED, which indicates the correct value, for each variable and each isolator.
- A red LED, which indicates the value in default, for each variable and each isolator.
- Two trimmers control the airflow for each isolator and another two control the pressure for each isolator.
- "on/off" switches start / stop pressure and airflow fan. One for each variable and for each isolator.
- An electronic key, switches on / off the unit.

### 3 SIGNATURES ARRAY:

Company	Function	Name	Date	Signature
NOROIT	Chairman	Gilles PAHE	23/07/09	
ESA / UAB	Maintenance technician	Raul MOYANO	23/07/09	
ESA/UAB	Laboratory technician	Cynthia Munganga	23/07/09	

### 4 DYNAMIC SAT TESTS EXECUTION

The execution of the dynamic SAT tests is performed on the site of the :  
 Departament de Enginyeria Química  
 Escola Tècnica Superior de Enginyeria (ETSE)  
 Universitat Autònoma de Barcelona  
 Campus de Bellaterra, Barcelona.

They are performed by Noroit and controlled by Ms. Munganga.

### 5 DYNAMIC TESTS LIST

- Test 1 : Control of the keyboard functions.
- Test 2 : Control of the colorsafe functionality.
- Test 3 : Control of the lift table.
- Test 4 : Control of the air cleanliness classification : ISO 5 – Class 100.
- Test 5 : Control of the pressure.
- Test 6 : Control of the airflow.
- Test 7 : Control of the temperature measurement.
- Test 8 : Control of the hygrometry measurement.

### 6 NON-COMPLIANCE HANDLING

In case of non compliance, for a test :

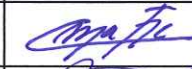

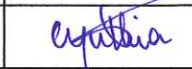
- In the array, chapter 9, « Results and observations summary », indicate the number of the non-compliance sheet in the case « Non-compliance sheet number ».
- Fill in the array, chapter 8, named « Non-compliance register ».
- Fill in the non-compliance sheet (see annex II)
- As corrective action, indicate redo action and the test number.
- Carry on the corrective action.
- Redo the test and fill the array, named « Non-compliance register ».

**7 FINAL RECEPTION :**

Final reception status :

**Acceptable**

**Non Acceptable**

Company	Function	Name	Date	Signature
NOROIT	Chairman	Gilles MAHE	23/07/09	
ESA / UAB	Maintenance technician	Raul MOYANO	23/07/09	
ESA/UAB	Laboratory technician	Cynthia Purganga	23/07/09	

**Comments :**

According with Noroit we are going to wait for the solution for the compensation of the weight on the top part of the isolator in order to have a good control of the lift table.















**8 NON-COMPLIANCE REGISTER :**










The following table summarizes the non-conformities of this module.  
Critical non conformities must be resolved before operating the unit.

Number of the non-compliance sheet	Number of the protocol section	Signature and date	Grade (Please circle the corresponding criteria)	Solution : date	Solution : Signature
2009-07-001	2009-07-001-PR	23/07/09 <i>[Signature]</i>	<u>CRITICAL</u> NON CRITICAL	23/07/09 Send mechanical parts to be installed at the back of the stand.	<i>[Signature]</i> Mech. parts received OK Eugene Peis 10.12.09 <i>[Signature]</i>
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		
			CRITICAL NON CRITICAL		


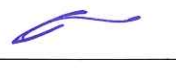







<b>TEST 1: Control of the keyboard functions :</b>		
Re-test : <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Check the correct functioning of the keyboard and associated functions.		
<b>PRE REQUIRED</b>		
Electrical connection of the equipment.		







**UP isolators :**

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Insert the key in A.	The displays flash	✓		23/07/09 
Press the button 4	The LED in the middle of the button flashes	✓		
Press the button 8	The LED in the middle of the button flashes	✓		
Press the button 12	The LED in the middle of the button flashes	✓		
Turn the knob 3 clockwise	The pressure in the transfer chamber increases	✓		
Turn the knob 7 clockwise	The airflow in the up isolator increases	✓		
Turn the knob 11 clockwise	The pressure in the up isolator increases	✓		
Increase the pressure in the transfer chamber over 70 Pa	The LED 2B flashes, after 10s delay	✓		
Decrease the pressure in the transfer chamber under 15 Pa	The LED 2B flashes, after 10s delay	✓		
Set the pressure in the transfer chamber between 15 and 70 Pa.	The LED 2A flashes	✓		
Increase the airflow in the isolator over 70 meter <sup>3</sup> /h.	The LED 6B flashes, after 10s delay.	✓		
Decrease the airflow in the isolator under 30 meter <sup>3</sup> /h	The LED 6B flashes, after 10s delay	✓		

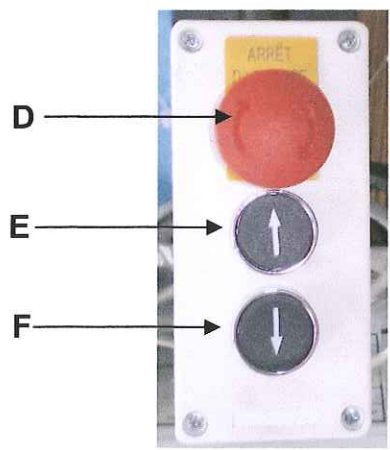
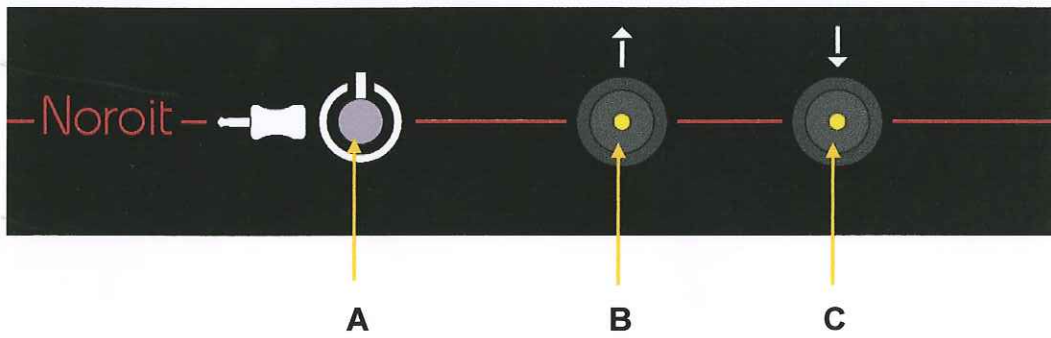
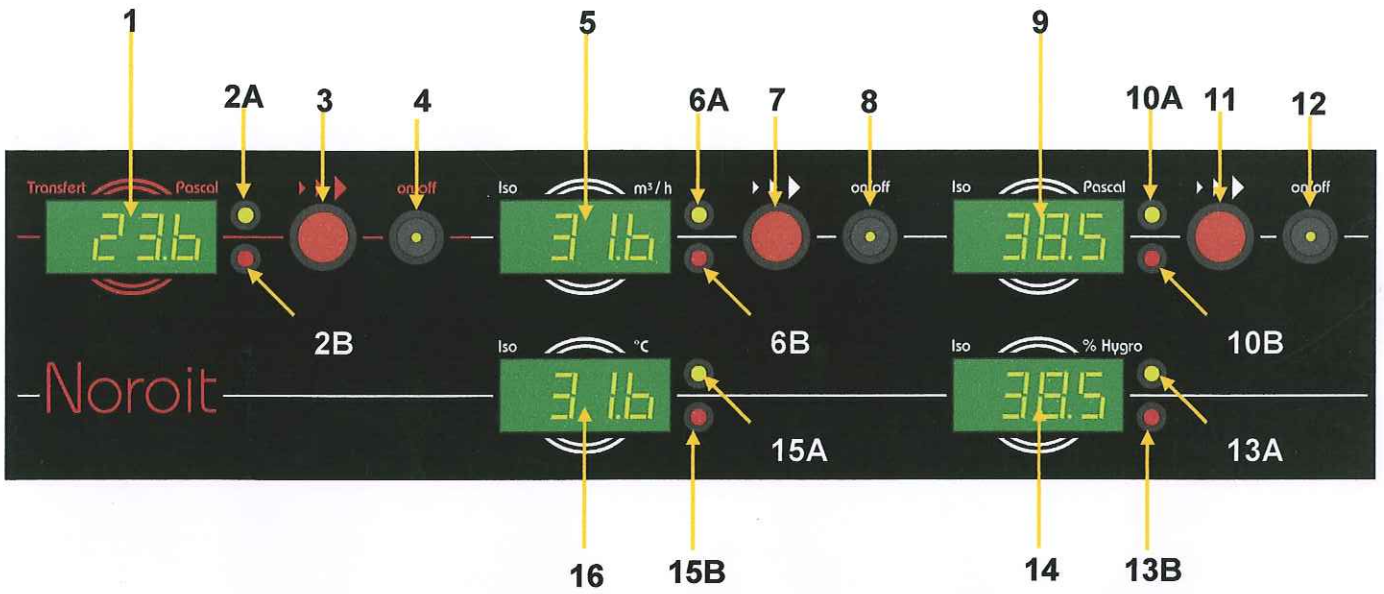
Set the airflow in the isolator between 30 and 70 meter <sup>3</sup> /h	The LED 6A flashes	✓		23/07/09 
Increase the pressure in the isolator over 75 Pa	The LED 10B flashes, after 10s delay	✓		
Decrease the pressure in the isolator under 25 Pa	The LED 10B flashes, after 10s delay	✓		
Put the pressure in the isolator between 25 and 75 Pa	The LED 10A flashes	✓		
Press the button B	The lift table goes up	✓		
Press the button C	The lift table goes down	✓		
Press the button E	The lift table goes up	✓		
Press the button F	The lift table goes down	✓		
Press the button D	Button B, C, E and F are inactive. The lift table do not move	✓		

**DOWN isolators :**

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Press the button 4	The LED in the middle of the button flashes	✓		23/07/09 
Press the button 8	The LED in the middle of the button flashes	✓		
Press the button 12	The LED in the middle of the button flashes	✓		
Turn the knob 3 clockwise	The pressure in the transfer chamber increases	✓		
Turn the knob 7 clockwise	The airflow in the up isolator increases	✓		
Turn the knob 11 clockwise	The pressure in the up isolator increases	✓		
Increase the pressure in the transfer chamber over 70 Pa	The LED 2B flashes, after 10s delay	✓		
Decrease the pressure in the transfer chamber under 15 Pa	The LED 2B flashes, after 10s delay	✓		
Set the pressure in the transfer chamber between 15 and 70 Pa.	The LED 2A flashes	✓		

Increase the airflow in the isolator over 70 meter <sup>3</sup> /h.	The LED 6B flashes, after 10s delay.	✓		
Decrease the airflow in the isolator under 30 meter <sup>3</sup> /h	The LED 6B flashes, after 10s delay	✓		
Set the airflow in the isolator between 30 and 70 meter <sup>3</sup> /h	The LED 6A flashes	✓		
Increase the pressure in the isolator over 75 Pa	The LED 10B flashes, after 10s delay	✓		
Decrease the pressure in the isolator under 25 Pa	The LED 10B flashes, after 10s delay	✓		
Put the pressure in the isolator between 25 and 75 Pa	The LED 10A flashes	✓		







**Comments :**

**TEST STATUS**

**ACCORDANCE**




**NO ACCORDANCE**

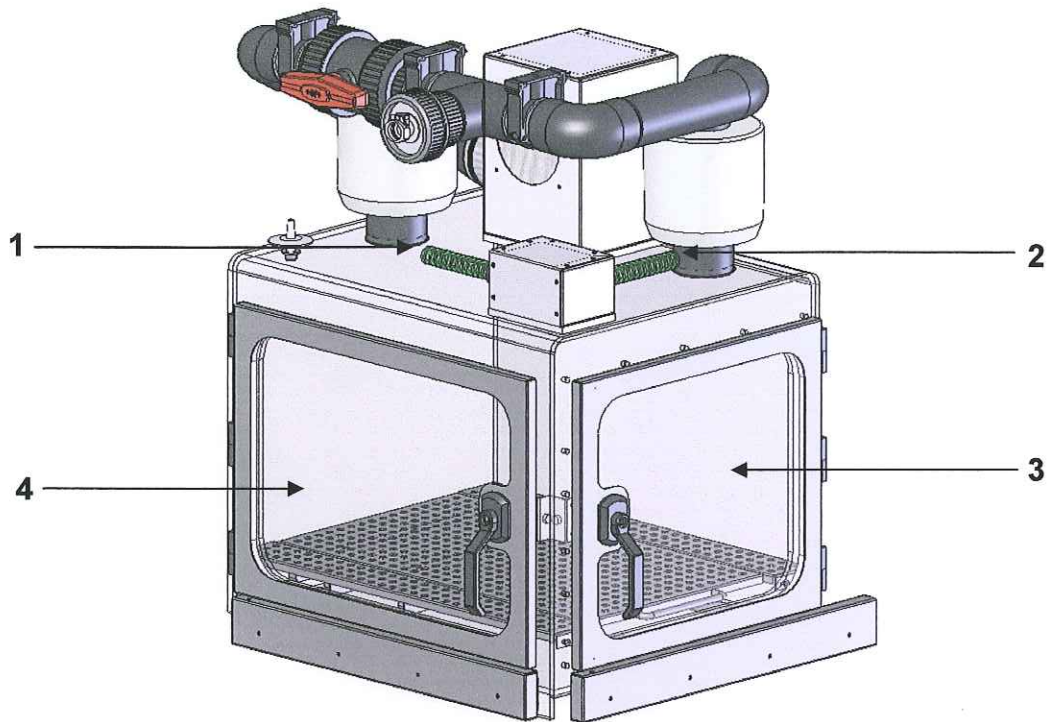
See sheet(s) of non-compliance number :

	Name	Company	Date	Signature
Tested by :	G. NAHE	NOROIT	23/07/09	
check by :	Raul MOYANG Cynthia NUNGANGA	ESA / UAB	23/07/09	

\* C = Compliance / NC = Non Compliance

<b>TEST 2 : Control of the colorsafe functionality</b>		
Re-test : <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Controls the functionality of the colorsafe system for each transfer chamber		
<b>PRE REQUIRED</b>		
Electrical connection of the equipment		

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Close the door 3 and 4	The bars 1 and 2 flash green.	✓		23/07/09 
Open the door 3, door 4 remains closed.	The bars 1 flashes red and the bar 2 flashes green.	✓		
Open the door 4, door 3 remains closed	The bars 1 flashes green and the bar 2 flashes red.	✓		





**Comments :**

**TEST STATUS**

**ACCORDANCE**


**NO ACCORDANCE**

See sheet(s) of non-compliance number :

	Name	Company	Date	Signature
Tested by :	G. MAHE	NOROIT	23/07/05	
check by :	RAUL MOYANO Cynthia MUNGABA	ESA / UAB	23/07/05	

\* C = Compliance / NC = Non Compliance

<b>TEST 3 : Control of the lift table</b>		
Re-test : <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Control the sensitive border of the lift table.		
<b>PRE REQUIRED</b>		
The lift table must be correctly supplied.		

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Press the sensitive border of the lift table. Press the C button to move down the lift table	The lift table does not move	ok		23/07/09 

**Comments :**

The lift table twists while moving up or down.  
Upper and lower positions are OK.

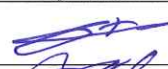

**TEST STATUS**

**ACCORDANCE**

**NO ACCORDANCE**

See sheet(s) of non-compliance number :

2009-07-001

	Name	Company	Date	Signature
Tested by :	Gilles MAHE	NOROIT	23/07/09	
check by :	Raul MOYANO Cynthia MUNGANGA	ESA / UAB	23/07/09	

\* C = Compliance / NC = Non Compliance



**TEST 4 : Control of the air cleanliness classification : ISO 5 – Class 100**

Re-test :  Yes  No

Re-test number :





Ref. Non-compliance(s) tested :

**OBJECTIVE**

Check the air cleanliness : class 100 inside the isolator.

**PRE REQUIRED**

Isolators must be running for at least 30 minutes.  
Particle counter available.

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Pre required : Install the sensor of the particle counter in the up isolator. Make the counting for one cubic feet. Print the results	Less than 100 particles of 0.3µm, per cubic feet.	ok		23/07/09 
Pre required : Install the sensor of the particle counter in the down isolator. Make the counting for one cubic feet. Print the results	Less than 100 particles of 0.3µm, per cubic feet.	ok		23/07/09 
Pre required : Install the sensor of the particle counter in the up transfer chamber. Make the counting for one cubic feet. Print the results	Less than 100 particles of 0.3µm, per cubic feet..	ok		23/07/09 
Pre required : Install the sensor of the particle counter in the down transfer chamber. Make the counting for one cubic feet. Print the results	Less than 100 particles of 0.3µm, per cubic feet.	ok		23/07/09 

Particle counter sensor installation in an isolator :

The particle counter sensor passes through a glove finger. The sealing is ensured by cable clamps.

The counting is performed in the transfer chamber with the communication door (door 3, see test 2) opened.



**Comments :**

**TEST STATUS**

**ACCORDANCE**

**NO ACCORDANCE**





See sheet(s) of non-compliance number :

	Name	Company	Date	Signature
Tested by :	Gilles MAHE	NOROIT	23/07/09	
check by :	Raul NOYANO Cyathia MUNGANGA	ESA / UAB	23/07/09	 Cyathia

\* C = Compliance / NC = Non Compliance



<b>TEST 5 : Control of the pressure</b>		
Re-test : <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Controls the pressure displayed for each isolator and for each transfer chamber		
<b>PRE REQUIRED</b>		
Electrical connection of the equipment. Isolators must be running		

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Install the sensor in the up isolator	The pressure measured and displayed on the control panel are the same $\pm 10\%$ .	✓		23/07/09 
Install the sensor in the down isolator	The pressure measured and displayed on the control panel are the same $\pm 10\%$ .	✓		
Install the sensor in the up transfer chamber	The pressure measured and displayed on the control panel are the same $\pm 10\%$ .	✓		
Install the sensor in the down transfer chamber	The pressure measured and displayed on the control panel are the same $\pm 10\%$ .	✓		

Pressure sensor installation in an isolator :

The pressure sensor passes through a glove finger. The sealing is ensured by cable clamps.

For the transfer chambers, the pressure sensor is connected after the "Millipore" absolute output filter.



**Comments :**

**TEST STATUS**

**ACCORDANCE**



**NO ACCORDANCE**

See sheet(s) of non-compliance number :

	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :	Gilles MAHE	NOROIT	23/07/09	
check by :	Raul MOYANO Guthie MUNGANGA	ESA / UAB	23/07/09	

\* C = Compliance / NC = Non Compliance

<b>TEST 6 : Control of the airflow</b>		
Re-test : <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Controls the airflow displayed for each isolator		
<b>PRE REQUIRED</b>		
Electrical connection of the equipment Isolators must be running		

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Install the sensor at the exhaust of the up isolator <i>front intake</i>	The airflow measured and displayed on the control panel are the same $\pm 10\%$ .	✓		23/07/09 
Install the sensor at the exhaust of the down isolator <i>front intake</i>	The airflow measured and displayed on the control panel are the same $\pm 10\%$ .	✓		

Airflow sensor installation :

The airflow sensor is installed at the exhaust of the isolator's ventilation network.

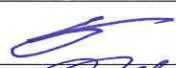


**Comments :**

**TEST STATUS**

**ACCORDANCE**

**NO ACCORDANCE**

See sheet(s) of non-compliance number :

	Name	Company	Date	Signature
Tested by :	Gilles MAHE	NOROIT	23/07/09	
check by :	Raul MOYANO Cynthia MUNGANDA	ESA / UAB	23/07/09	 

\* C = Compliance / NC = Non Compliance

<b>TEST 7 : Control of the temperature</b>		
Re-test : <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Controls the temperature displayed for each isolator		
<b>PRE REQUIRED</b>		
Electrical connection of the equipment Isolators must be running		

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Install the sensor in the up isolator	The temperature measured and displayed on the control panel are the same $\pm 10\%$ .	✓		23/07/09
Install the sensor in the down isolator	The temperature measured and displayed on the control panel are the same $\pm 10\%$ .	✓		23/07/09

Temperature sensor installation :  
 The temperature sensor passes through a glove finger. The sealing is ensured by cable clamps.  
 The temperature is measured close to the isolator's probe.



**Comments :**

---

**TEST STATUS**

**ACCORDANCE**                       **NO ACCORDANCE**



See sheet(s) of non-compliance number :

	Name	Company	Date	Signature
Tested by :	Gilles MAHE	NOROIT	23/07/09	
check by :	Raul MOYANO Guthia MUNGANGA	ESA / UAB	23/07/09	

\* C = Compliance / NC = Non Compliance



<b>TEST 8 : Control of the hygrometry</b>		
Re-test : <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Re-test number :	Ref. Non-compliance(s) tested :
<b>OBJECTIVE</b>		
Controls the hygrometry displayed for each isolator		
<b>PRE REQUIRED</b>		
Electrical connection of the equipment Isolators must be running		

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Install the sensor in the up isolator	The hygrometry rate measured and displayed on the control panel are the same <del>± 20%</del> <u>± 10%</u>	✓		23/07/09 
Install the sensor in the down isolator	The hygrometry rate measured and displayed on the control panel are the same <del>± 20%</del> <u>± 10%</u>	✓		

**Hygrometry sensor installation :**

The hygrometry sensor passes through a glove finger. The sealing is ensured by cable clamps.  
The hygrometry is measured close to the isolator's probe.



**Comments :**

**TEST STATUS**

**ACCORDANCE**

**NO ACCORDANCE**

See sheet(s) of non-compliance number :



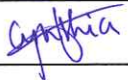
	Name	Company	Date	Signature
Tested by :	Gilles MAHE	NOROIT	23/07/09	
check by :	Raul MOYANO Gertie MUNGANGA	ESA / UAB	23/07/09	

\* C = Compliance / NC = Non Compliance





**Synthesis approval :**

Company	Function	Name	Date	Signature
NOROIT	Chairman	MAHE	23/07/09	
ESA / UAB	Maintenance tech.	MOYANO	23/07/09	
ESA / UAB	Laboratory tech.	MUNGANGA	23/07/09	



**10 ADDENDUM :**

Addendum I

Documentation attached

Addendum II

Non-compliance dynamic SAT report

<b>Addendum I : DOCUMENTATION ATTACHED</b>	<b>Page number</b>

**ANNEXE II : Non-compliance dynamic SAT report**

Module / System : Isolator

Description : isolator ESA Barcelona

Report number : 2009-07-001

Reference protocol number : 2009-07-001 - PR.

**1. Non-compliance description :**

The lift table twists while moving up or down because the weight is not well balanced on the top electrical compartment.  
Noticed by :

Name

Gilles MAHE

Signature



Date

23/07/09

**2. Non-compliance classification (tick the appropriate box) :**

Critical non-compliance:

Non-critical non-compliance:

Additional document for classification:

Classified by :

Gilles MAHE Noroit

Name / Department

Signature



Date

23/07/09

Name / Department

Signature

Date

**3. Corrective action :**

Mechanical parts must be installed at the back of the up stand to compensate the front weight. To be sent before September, 20th, 2009, by Noroit.  
Description of the tests performed :

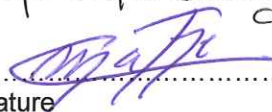
Counterweights are installed. UP/Down tests are performed.

UP/down test successful except slight bending in middle position. To be checked with platform supplier, and MPP team.

Name

Gilles MAHE

Signature



Date

10/12/09

Approved by :

ENRIQUE PEIRO

Name / Department

Signature

Enrique Peiro

Date

10/12/09

**ANNEXE II : Non-compliance dynamic SAT report**

Module / System : Isolator

Description : .....

Report number : .....

Reference protocol number : .....

**4. Non-compliance description :**

.....  
.....

Noticed by :

.....  
Name Signature Date

**5. Non-compliance classification (tick the appropriate box) :**

Critical non-compliance:  Non-critical non-compliance:

Additional document for classification:

.....

Classified by :

.....  
Name / Department Signature Date

.....  
Name / Department Signature Date

**6. Corrective action :**

.....  
.....

Description of the tests performed :

.....

Performed by :

.....  
Name Signature Date

Approved by :

.....  
Name / Department Signature Date



\*\*\*\*\* AIR FLOW ALARM \*\*\*\*\*

LOCATION 000, 17:39:20 DEC 10,09

CYCLES = 005, PERIOD = 00:01:00

SIZE CUMULATIVE DIFFERENTIAL

0.3u 0 0

0.5u 0 0

0.7u 0 0

1.0u 0 0

3.0u 0 0

5.0u 0 0

Down

LOCATION 000, 17:40:21 DEC 10,09

CYCLES = 005, PERIOD = 00:01:00

SIZE CUMULATIVE DIFFERENTIAL

0.3u 0 0

0.5u 0 0

0.7u 0 0

1.0u 0 0

3.0u 0 0

5.0u 0 0

\*\*\*\*\* AIR FLOW ALARM \*\*\*\*\*

LOCATION 000, 17:41:22 DEC 10,09

CYCLES = 005, PERIOD = 00:01:00

SIZE CUMULATIVE DIFFERENTIAL

0.3u 3 3

0.5u 0 0

0.7u 0 0

1.0u 0 0

3.0u 0 0

5.0u 0 0

LOCATION 000, 17:42:23 DEC 10,09

CYCLES = 005, PERIOD = 00:01:00

SIZE CUMULATIVE DIFFERENTIAL

0.3u 1 1

0.5u 0 0

0.7u 0 0

1.0u 0 0

3.0u 0 0

5.0u 0 0

LOCATION 000, 19:14:52 DEC 10,09

CYCLES = 005, PERIOD = 00:01:00

SIZE CUMULATIVE DIFFERENTIAL

0.3u 11 4

0.5u 7 0

0.7u 7 3

1.0u 4 3

3.0u 1 1

5.0u 0 0

Up

LOCATION 000, 19:15:53 DEC 10,09

CYCLES = 005, PERIOD = 00:01:00

SIZE CUMULATIVE DIFFERENTIAL

0.3u 1 0

0.5u 1 1

0.7u 0 0

1.0u 0 0

3.0u 0 0

5.0u 0 0

LOCATION 000, 19:16:54 DEC 10,09

CYCLES = 005, PERIOD = 00:01:00

SIZE CUMULATIVE DIFFERENTIAL

0.3u 0 0

0.5u 0 0

0.7u 0 0

1.0u 0 0

3.0u 0 0

5.0u 0 0

LOCATION 000, 19:17:55 DEC 10,09

CYCLES = 005, PERIOD = 00:01:00

SIZE CUMULATIVE DIFFERENTIAL

0.3u 0 0

0.5u 0 0

0.7u 0 0

1.0u 0 0

3.0u 0 0

5.0u 0 0

LOCATION 000, 19:18:56 DEC 10,09

CYCLES = 005, PERIOD = 00:01:00

SIZE CUMULATIVE DIFFERENTIAL

0.3u 4 1

0.5u 3 0

0.7u 3 0

1.0u 3 1

3.0u 2 2

5.0u 0 0

LOCATION 000, 11:19:20 JUL 23,09  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL  
 0.3u 19 UP 16  
 0.5u 3 ISOLATOR 1  
 0.7u 0 0  
 1.0u 2 1  
 3.0u 1 1  
 5.0u 0 0

LOCATION 000, 11:20:21 JUL 23,09  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL  
 0.3u 5 5  
 0.5u 0 0  
 0.7u 0 0  
 1.0u 0 0  
 3.0u 0 0  
 5.0u 0 0

LOCATION 000, 11:21:22 JUL 23,09  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL  
 0.3u 4 4  
 0.5u 0 0  
 0.7u 0 0  
 1.0u 0 0  
 3.0u 0 0  
 5.0u 0 0

LOCATION 000, 11:22:23 JUL 23,09  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL  
 0.3u 1 1  
 0.5u 0 0  
 0.7u 0 0  
 1.0u 0 0  
 3.0u 0 0  
 5.0u 0 0

LOCATION 000, 11:23:24 JUL 23,09  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL  
 0.3u 4 4  
 0.5u 0 0  
 0.7u 0 0  
 1.0u 0 0  
 3.0u 0 0  
 5.0u 0 0

LOCATION 000, 11:56:15 JUL 23,09  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL  
 0.3u 1 UPSAS 1  
 0.5u 0 0  
 0.7u 0 0  
 1.0u 0 0  
 3.0u 0 0  
 5.0u 0 0

\*\*\*\*\* AIR FLOW ALARM \*\*\*\*\*  
 LOCATION 000, 11:57:16 JUL 23,09  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL  
 0.3u 0 0  
 0.5u 0 0  
 0.7u 0 0  
 1.0u 0 0  
 3.0u 0 0  
 5.0u 0 0

LOCATION 000, 12:30:10 JUL 23,09  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL  
 0.3u 10 3  
 0.5u 7 2  
 0.7u 5 0  
 1.0u 5 4  
 3.0u 1 1  
 5.0u 0 0

LOCATION 000, 12:31:11 JUL 23,09  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL  
 0.3u 1 1  
 0.5u 0 0  
 0.7u 0 0  
 1.0u 0 0  
 3.0u 0 0  
 5.0u 0 0

\*\*\*\*\* AIR FLOW ALARM \*\*\*\*\*  
 LOCATION 000, 12:32:12 JUL 23,09  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL  
 0.3u 1 0  
 0.5u 1 DOWN 0  
 0.7u 1 ISOLATOR 0  
 1.0u 1 0  
 3.0u 1 1  
 5.0u 0 0

LOCATION 000, 12:33:13 JUL 23,09  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL  
 0.3u 4 1  
 0.5u 3 0  
 0.7u 3 0  
 1.0u 3 1  
 3.0u 2 2  
 5.0u 0 0

\*\*\*\*\* AIR FLOW ALARM \*\*\*\*\*  
 LOCATION 000, 12:34:14 JUL 23,09  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL  
 0.3u 0 0  
 0.5u 0 0  
 0.7u 0 0  
 1.0u 0 0  
 3.0u 0 0  
 5.0u 0 0

\*\*\*\*\* AIR FLOW ALARM \*\*\*\*\*  
 LOCATION 000, 12:45:30 JUL 23,09  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL  
 0.3u 1 1  
 0.5u 0 0  
 0.7u 0 0  
 1.0u 0 DOWN 0  
 3.0u 0 SAS 0  
 5.0u 0 0

\*\*\*\*\* AIR FLOW ALARM \*\*\*\*\*  
 LOCATION 000, 12:46:31 JUL 23,09  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL  
 0.3u 1 1  
 0.5u 0 0  
 0.7u 0 0  
 1.0u 0 0  
 3.0u 0 0  
 5.0u 0 0





The breath of protection

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**TECHNICAL SPECIFICATION**

**50032 A**

**LEAK TEST :  
PRESSURE DECAY PER TIME**






**DESCRIPTION :**

**LEAK TEST : PRESSURE DECAY PER TIME.**

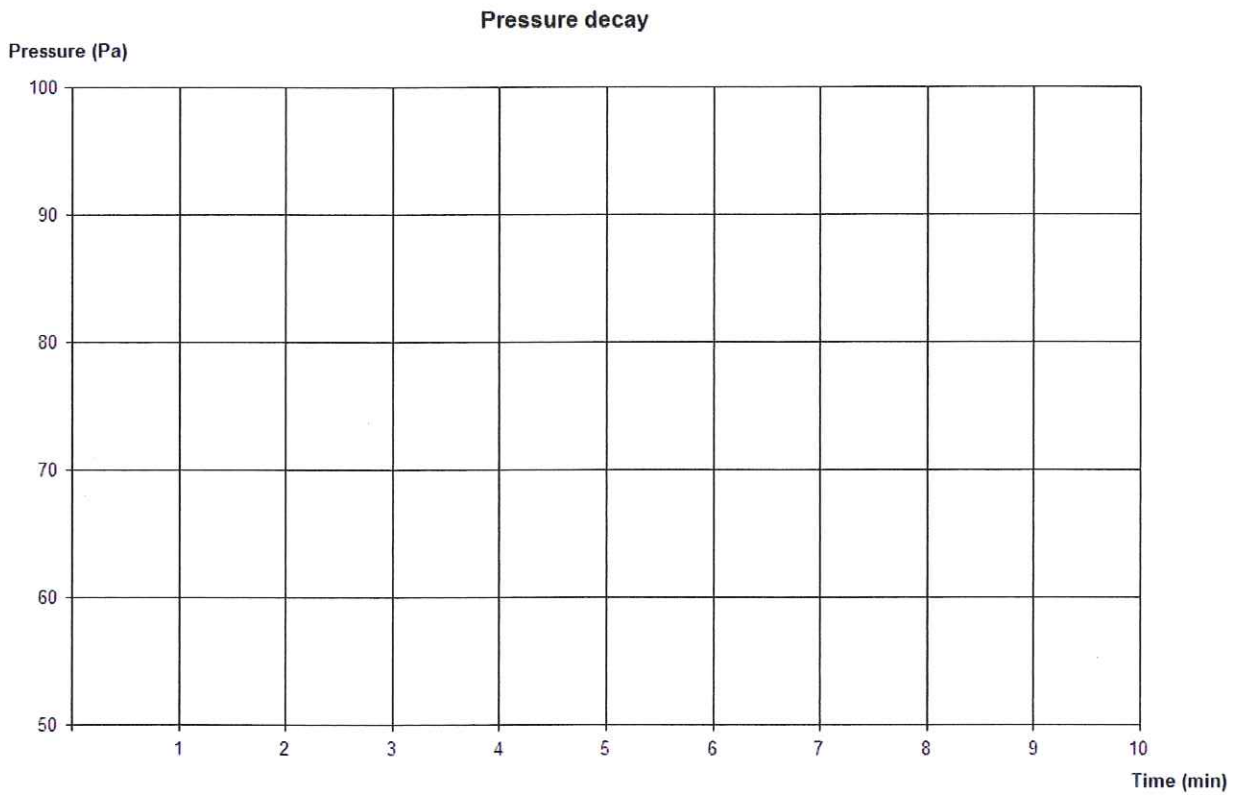
Controls the tightness of the isolator

**PRE REQUIRED**

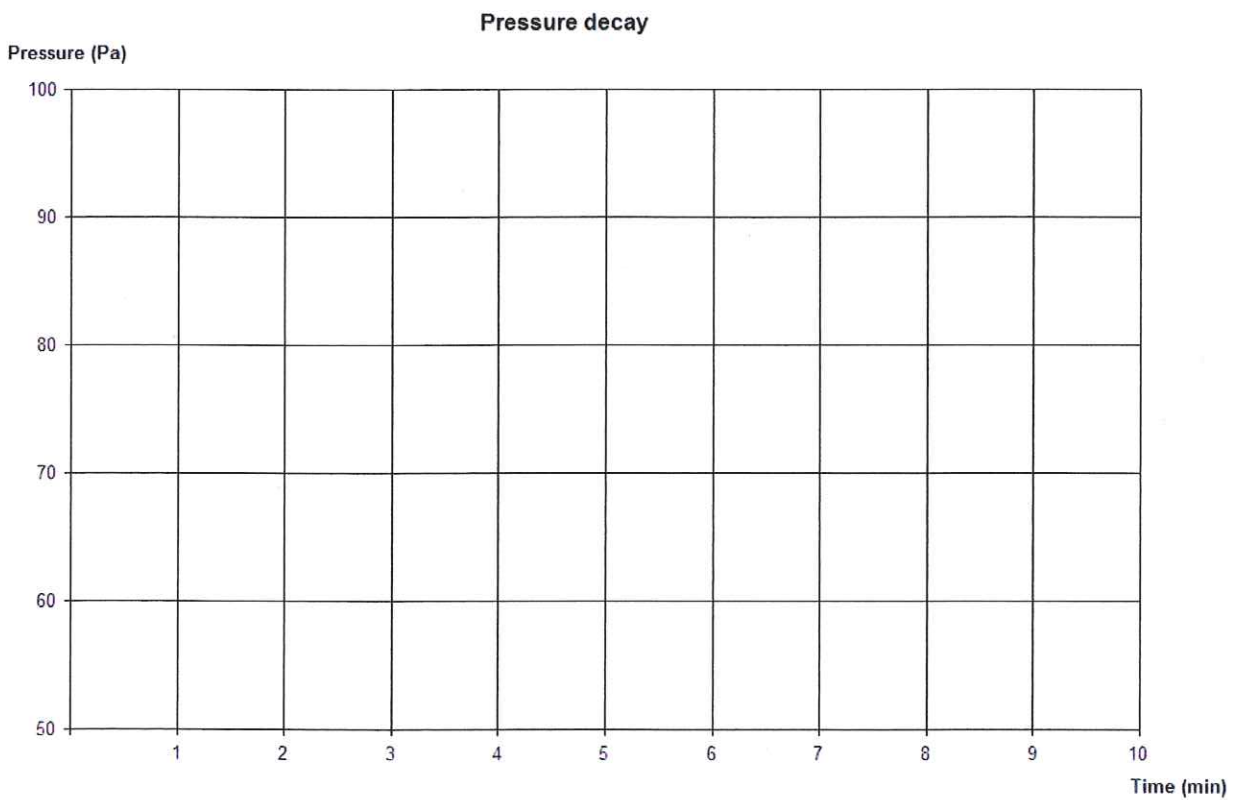
Electrical connection of the equipment.  
Isolators must be running.

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
1 Set the positive pressure inside the up isolator to 100 Pa. To achieve this, use the airflow knob only. The pressure fan must be switched off.	100 Pa $\pm$ 10% is displayed on the control panel.	OK	C <del>NC</del>	
2 The isolator must be left running for at least 5 minutes, time enough for the pressure to stabilize.	100 Pa $\pm$ 10% is displayed on the control panel.	OK	C <del>NC</del>	
3 Set the 2 position valves, normally used for sterilization, to the closed position. This procedure will totally isolate the up isolator from the ventilation network.	--	OK	<del>C</del> L	
4 Switch off the fan.	--	OK	C	
5 Wait for 10 minutes. Note the pressure value displayed, every minute.	After 10 minutes, the displayed value must not drop below 75 Pa	Up : 30 Pa down : 35 Pa	NC	
6 Same procedure for the down isolator.				

**Graph -- UP isolator :**



**Graph -- DOWN isolator :**




**Comments :**

**TEST STATUS :**

**ACCORDANCE**

**NO ACCORDANCE**

:

	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :	G. MAHE	NOROIT	10/12/09	
check by :	E. PETRO	ESA / UAB	10.12.09	<u>E. Petro</u>



The breath of protection

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**TECHNICAL SPECIFICATION**

**50032 A**

**LEAK TEST :  
PRESSURE DECAY PER TIME**



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**TECHNICAL SPECIFICATION**

**50032 A**

**LEAK TEST :  
PRESSURE DECAY PER TIME**



DESCRIPTION :

**LEAK TEST : PRESSURE DECAY PER TIME.**

Controls the tightness of the isolator

**PRE REQUIRED**

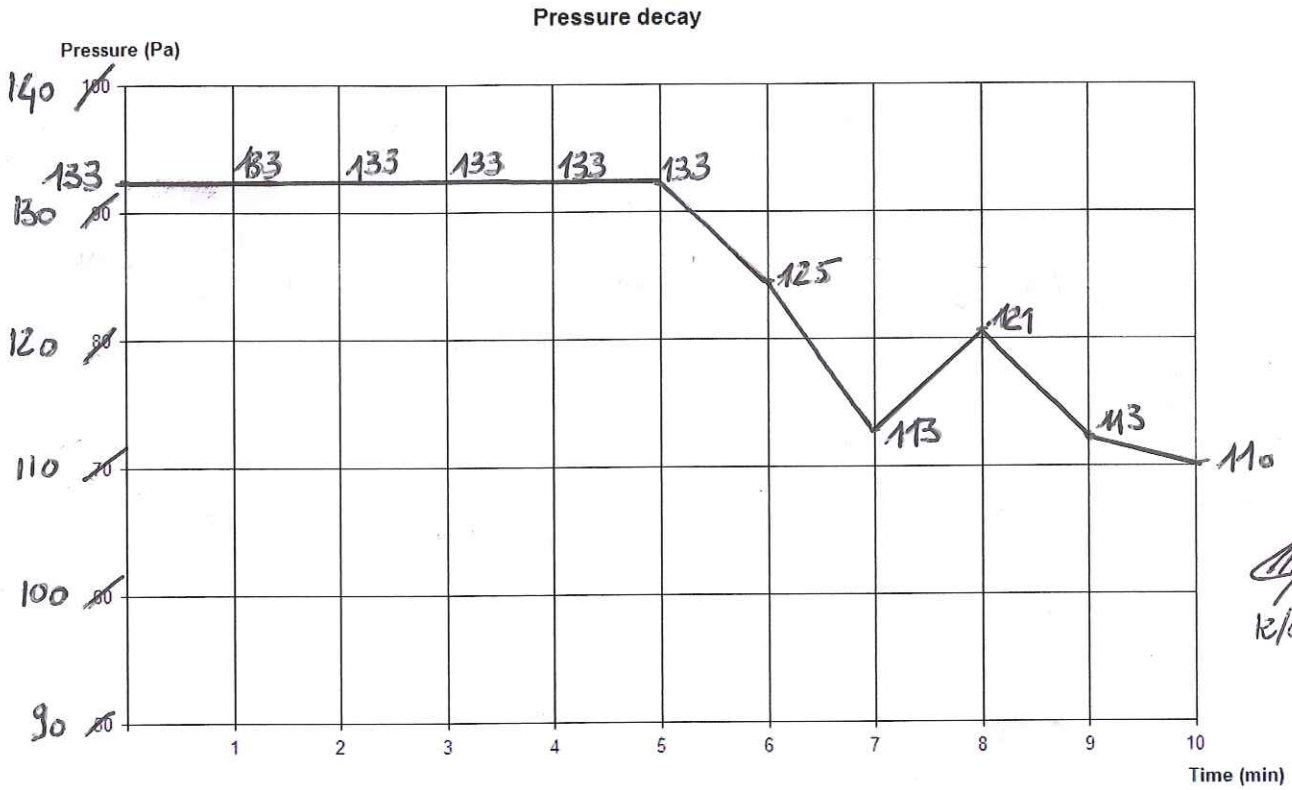
Electrical connection of the equipment.  
Isolators must be running.

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
1 Set the positive pressure inside the up isolator to 100 Pa. To achieve this, use the airflow knob only. The pressure fan must be switched off.	<i>125 (12/03/2010)</i> 100 Pa $\pm$ 10% is displayed on the control panel.	OK	C	12/03/2010 <i>[Signature]</i>
2 The isolator must be left running for at least 5 minutes, time enough for the pressure to stabilize.	<i>125 (12/03/2010)</i> 100 Pa $\pm$ 10% is displayed on the control panel.	OK	C	<i>[Signature]</i>
3 Set the 2 position valves, normally used for sterilization, to the closed position. This procedure will totally isolate the up isolator from the ventilation network.	--	OK	C	<i>[Signature]</i>
4 Switch off the fan.	--	OK	C	<i>[Signature]</i>
5 Wait for 10 minutes. Note the pressure value displayed, every minute.	After 10 minutes, the displayed value must not drop below 75 Pa	OK	C	<i>[Signature]</i>
6 Same procedure for the down isolator.	100 <i>[Signature]</i>	OK	C	<i>[Signature]</i>

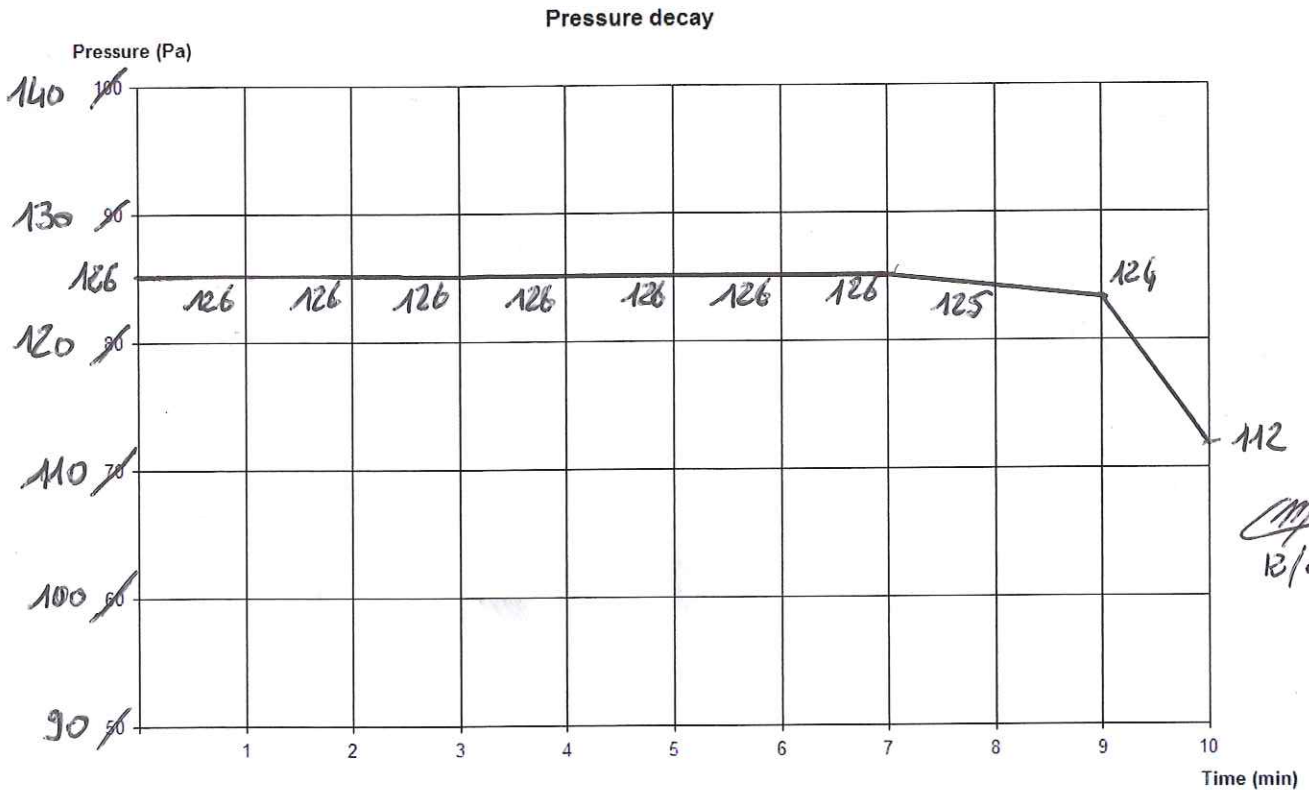
*12/03/2010*



Graph -- UP isolator :



Graph -- DOWN isolator :


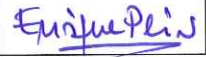


**Comments :**

**TEST STATUS :**

**ACCORDANCE**

**NO ACCORDANCE**

	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :	G. NAHE	NOROIT	12/03/2010	
check by :	E. PEIRO	ESA / UAB	12/03/2010	



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**TECHNICAL SPECIFICATION**

**50046 A**

**PARTICLE COUNTING  
INSIDE THE ISOLATORS :**

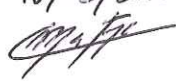

**Control of the air cleanliness classification : ISO 5 – Class 100**

**OBJECTIVE**

Check the air cleanliness : class 100 inside the isolator.

**PRE REQUIRED**

Isolators must be running for at least 30 minutes.  
Particle counter available.

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Pre required : Install the sensor of the particle counter in the up isolator. Make the counting for one cubic feet. Print the results	Less than 100 particles of 0.3µm, per cubic feet.	OK	C	18/03/2010 
Pre required : Install the sensor of the particle counter in the down isolator. Make the counting for one cubic feet. Print the results	Less than 100 particles of 0.3µm, per cubic feet.	OK	C	

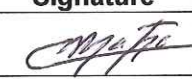
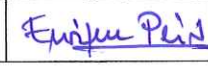
**Comments :**

**TEST STATUS**

**ACCORDANCE**

**NO ACCORDANCE**

See sheet(s) of non-compliance number :

	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>
Tested by :	G. MAHE	NOROIT	12/03/10	
check by :	E. PEIRO	ESA / UAB	12/03/10	

\* C = Compliance / NC = Non Compliance

\*\*\*\*\* AIR FLOW ALARM \*\*\*\*\*  
 LOCATION 032, 11:17:42 MAR 12,10  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL

0.3um	20	14
0.5um	6	4
1.0um	2	2
3.0um	0	0
5.0um	0	0
10. um	0	0

DOWN

\*\*\*\*\* AIR FLOW ALARM \*\*\*\*\*  
 LOCATION 032, 11:18:42 MAR 12,10  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL

0.3um	6	5
0.5um	1	0
1.0um	1	1
3.0um	0	0
5.0um	0	0
10. um	0	0

\*\*\*\*\* AIR FLOW ALARM \*\*\*\*\*  
 LOCATION 032, 11:19:42 MAR 12,10  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL

0.3um	2	2
0.5um	0	0
1.0um	0	0
3.0um	0	0
5.0um	0	0
10. um	0	0

\*\*\*\*\* AIR FLOW ALARM \*\*\*\*\*  
 LOCATION 032, 11:20:42 MAR 12,10  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL

0.3um	2	2
0.5um	0	0
1.0um	0	0
3.0um	0	0
5.0um	0	0
10. um	0	0

\*\*\*\*\* AIR FLOW ALARM \*\*\*\*\*  
 LOCATION 032, 11:21:42 MAR 12,10  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL

0.3um	1	1
0.5um	0	0
1.0um	0	0
3.0um	0	0
5.0um	0	0
10. um	0	0

\*\*\*\*\* AIR FLOW ALARM \*\*\*\*\*  
 LOCATION 032, 12:01:40 MAR 12,10  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL

0.3um	28	27
0.5um	1	1
1.0um	0	0
3.0um	0	0
5.0um	0	0
10. um	0	0

\*\*\*\*\* AIR FLOW ALARM \*\*\*\*\*  
 LOCATION 032, 12:02:40 MAR 12,10  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL

0.3um	21	18
0.5um	3	2
1.0um	1	1
3.0um	0	0
5.0um	0	0
10. um	0	0

\*\*\*\*\* AIR FLOW ALARM \*\*\*\*\*  
 LOCATION 032, 12:03:40 MAR 12,10  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL

0.3um	13	12
0.5um	1	1
1.0um	0	0
3.0um	0	0
5.0um	0	0
10. um	0	0

\*\*\*\*\* AIR FLOW ALARM \*\*\*\*\*  
 LOCATION 032, 12:04:40 MAR 12,10  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL

0.3um	0	0
0.5um	0	0
1.0um	0	0
3.0um	0	0
5.0um	0	0
10. um	0	0

\*\*\*\*\* AIR FLOW ALARM \*\*\*\*\*  
 LOCATION 032, 12:05:40 MAR 12,10  
 CYCLES = 005, PERIOD = 00:01:00  
 SIZE CUMULATIVE DIFFERENTIAL

0.3um	7	7
0.5um	0	0
1.0um	0	0
3.0um	0	0
5.0um	0	0
10. um	0	0



# Service Technique PMT France

## DOSSIER METROLOGIQUE

Réf. 09040632/033      MET ONE 2400

Germany · Benelux · Together we create Solutions · France · GB



## CERTIFICAT D'ETALONNAGE N°09040632/033

**Client** : Noroit Labo / ADM Labo Serv

**Contact** : P. Sidaner

**Adresse** : 2, rue Robert Schuman  
44400 Rezé

**Téléphone** : 02.40.50.12.77

**Étalonné le** : 06 Avril 2009

**Date d'expiration** : 06 Avril 2010

**Instrument étalonné :**

Modèle	MET ONE 2400	Fabricant	MET ONE
N° de série	20040097	Plage de mesure	0.3 – 25 µm
N°identification client	N/A	Lieu de l'étalonnage	En nos locaux
Remarque	Prévoir remplacement du filtre interne au prochain étalonnage. Mise à jour software 2.06 -> 2.2.2		

**Matériels utilisés:**

Désignation	Modèle	Numéro de série	Date d'expiration
Générateur de particules	PMS PG-100	NA	NA
Filtre absolu de 0.2µ	FL37	NA	NA
Débitmètre	SIERRA S730	83012	26 février 2010
Multimètre	METRIX MX53C	196101VAX	06 Juin 2009
Compteur de référence	PMS LASAIR II 310A	60064	09 Mai 2009

**Particules utilisées:** Type microsphère de latex ( traçable par le National Institute of Standards & Technology)

Diamètre nominal	Diamètre réel	N° de lot	Date d'expiration
0.3 µm	300nm	32975	Février 2011
0.5 µm	491nm	30841	Novembre 2009
1.0 µm	0.994 µm	33059	Février 2011
5.0 µm	5.0 µm	32880	Janvier 2011
10.0 µm	10.0 µm	33081	Mars 2011
25.0 µm	25.6 µm	32782	Décembre 2010

*PMT France certifie que l'instrument ci-dessus a fait l'objet d'un étalonnage utilisant des équipements et des standards certifiés. Il répond à cette date, à toutes les caractéristiques du constructeur.*

Rédigé par : M. CHARLES Rodolphe

Vérifié par :

Fait le : 06 Avril 2009

Fait le :

M. MARTIAL Joel

06 Avril 2009

Signature :



Signature :




**PROCEDURE MET ONE 2400** Revision 2.0 - Décembre 2008

INSTRUMENT S/N: 2400 0097

MESURES AVANT REGLAGE

Particule split	Taille de particule µm	Tolérance du split	Valeur du split			Tolérance	
			Mesure 1	Mesure 2	Mesure 3	C	N.C
	5	0.48 - 1.71	0,98	1,02	1,04	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Particule split	Taille de particule µm	Tolérance du split	Valeur du split			Tolérance	
			Mesure 1	Mesure 2	Mesure 3	C	N.C
	0.5	0.38 - 2.74	0,97	0,93	0,97	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Sensibilité	Taille de particule µm	Tolérance de la sensibilité	Valeur de la sensibilité			Tolérance	
			Mesure 1	Mesure 2	Mesure 3	C	N.C
	0.3	101 - 235%	198 %	192 %	195 %	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comptage zéro	Temps		10 min			Tolérance	
	Conforme		< 2 <input checked="" type="checkbox"/>			C	N.C
	Non Conforme		> 1 <input type="checkbox"/>			<input checked="" type="checkbox"/>	<input type="checkbox"/>
Débit	Tolérance du débit		Débit de l'appareil			Tolérance	
	1.76 CFM +/- 5%		1,73	CFM		<input checked="" type="checkbox"/>	<input type="checkbox"/>

STATUT DE L'APPAREIL: CONFORME  NON CONFORME  MESURE IMPOSSIBLE

MESURES APRES REGLAGE

Particule split	Taille de particule µm	Tolérance du split	Valeur du split			Tolérance		
			Mesure 1	Mesure 2	Mesure 3	C	N.C	
	25	0.91 - 1.10	0,99	1,00	1,04	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Particule split	Taille de particule µm	Tolérance du split	Valeur du split			Tolérance		
			Mesure 1	Mesure 2	Mesure 3	C	N.C	
	10	0.91 - 1.10	1,04	1,03	0,97	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Particule split	Taille de particule µm	Tolérance du split	Valeur du split			Tolérance		
			Mesure 1	Mesure 2	Mesure 3	C	N.C	
	5	0.91 - 1.10	1,06	1,00	1,02	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Particule split	Taille de particule µm	Tolérance du split	Valeur du split			Tolérance		
			Mesure 1	Mesure 2	Mesure 3	C	N.C	
	1.0	0.91 - 1.10	0,95	0,95	0,98	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Particule split	Taille de particule µm	Tolérance du split	Valeur du split			Tolérance		
			Mesure 1	Mesure 2	Mesure 3	C	N.C	
	0.5	0.91 - 1.10	1,05	1,04	0,93	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Sensibilité	Taille de particule µm	Tolérance de la sensibilité	Valeur de la sensibilité			Tolérance		
			Mesure 1	Mesure 2	Mesure 3	C	N.C	
	0.3	151 - 185%	178 %	176 %	175 %	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Efficacité	Taille de particule µm	Tolérance de l'efficacité	Valeur de l'efficacité de comptage			Tolérance		
			Mesure 1	Mesure 2	Mesure 3	C	N.C	
	0.5	151 - 185%	169 %	165 %	165 %	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Comptage zéro	Temps		25 min	50 min	75 min	100 min	Tolérance	
	Conforme		< 2 <input checked="" type="checkbox"/>	< 6 <input type="checkbox"/>	< 11 <input type="checkbox"/>	< 20 <input type="checkbox"/>	C	N.C
	Non Conforme		> 9 <input type="checkbox"/>	> 14 <input type="checkbox"/>	> 19 <input type="checkbox"/>	> 19 <input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Débit	Tolérance du débit		Débit de l'appareil			Tolérance		
	1.76 CFM +/- 5%		1,76	CFM		<input checked="" type="checkbox"/>	<input type="checkbox"/>	

STATUT DE L'APPAREIL: CONFORME  NON CONFORME

Etalonné par: *M. CHIFFRES Rodolphe*

Signature: *[Signature]*

Date: 06 Avril 2009

Germany - Benelux - Together we create solutions France - UK

## **10. POST-SALE SERVICE CONTRACT AND CONSUMABLE PARTS PROPOSAL**

- **Post-sale service and spares contract**
- **Water network installation proposal**
- **Spare parts price list**



Le souffle protecteur

**Noroit**

« Rezé créatic »,  
2 rue Robert Schuman  
44408 Rezé Cedex

Tél. : 02.40.50.12.77

Fax : 02.51.70.20.25

contact@noroitlabo.com

[www.noroitlabo.com](http://www.noroitlabo.com)

## ***Post sale service contract***

***Escuela Tecnica Superior de Ingenieria (ETSE)***

***Universidad Autonoma de Barcelona***

***Departamento de Enginyeria Quimica***

***Campus de Bellaterra (Barcelona)***

March, 4<sup>th</sup> 2010

Contract No. 0811132 C

Noroit Sarl , au capital de 94 710 EUR

RCS Nantes B 492 601 349, SIRET 492 601 349 00029, Code APE 3250A, TVA FR 38 492 601 349

## CONDITIONS

### 1/ VISIT CONTRACT:

An annual visit is included in this contract. The exact date will be defined together with the customer. This visit will include the following tests and potential modifications, depending upon the tests results :

- Visual inspection of the equipment, including the sleeves and fluid ports.
- Visual inspection of the ventilation networks.
- Qualitative pressure test.
- Quantitative pressure test.
- Control of the air cleanliness classification : ISO 5 – Class 100.
- Lift table maintenance.

These tests are described in details, further in this document.

The quantitative test and control of the air cleanliness must be successful, after this visit. Otherwise, Noroit will provide additional intervention to guarantee these requirements, without additional charge for the customer.

Control reports will be delivered to the customer.



### 1.1 Qualitative pressure test description :

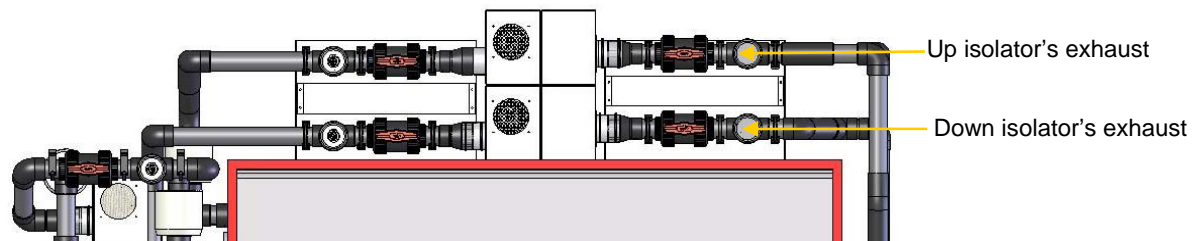
This test involves an ammonia solution and a special silk cloth detecting NH<sub>3</sub>.

This test is very reliable to detect micro-leaks on the air network and connections.

Equipment used in the test, provided by Noroit :

- A bottle of ammonia alkali solution.
- A plastic flat bowl.
- A funnel.
- Special cloth detecting NH<sub>3</sub>.
- Paper towels.
- A plastic bag equipped with an hermetic seal.
- A flexible pipe, Ø 63mm, connected to a plastic manual valve on one side and to a threaded connector on the other side. The valve is used to clog the exhaust, in order to easily reach a high pressure inside the isolator while limiting the airflow.

This flexible pipe must be connected to the isolator's exhaust, using the threaded connector.



UAB must provide a Ø 63mm flexible pipe. One end will be connected to the manual valve (to be performed by Noroit), the other pipe's end must be connected to the outside of the laboratory (to be performed by UAB).

Noroit delivered on March, 2<sup>nd</sup>, 2010 the safety data sheet regarding the *ammonia alkali 13%* used.

The following elements are now entered into the isolator :

- The bottle of ammonia alkali solution.
- The plastic flat bowl.
- The funnel.
- The paper towels.

The flat bowl is positioned at the centre of the isolator, on several slices of paper towels.

A 100 Pa positive pressure is then applied inside the isolator, using both the isolator's keyboard and the exhaust valve. Ten centiliters of ammonia is then poured inside the flat bowl.

The gas will progressively saturates the isolator's chamber. The isolator is left running for 10 minutes; time enough for the ammonia to spread inside the whole volume. The special silk cloth is then applied around the hard and soft PVC network and connections, to detect potential leaks. The special silk cloth gets coloured in green whenever small amounts of ammonia are detected. Detected leaks will be clearly indicated on the network, using coloured stickers.

After completion of this procedure, the ammonia is poured back into the bottle, using the funnel. The work tray and the funnel are then totally wiped up by the towel, to remove every drop of ammonia. The towels are then positioned into the plastic bag, which is then hermetically sealed.

The airflow is then set to its maximum, to flush the isolator. The exhaust valve is widely opened.

After a some minutes, we may consider that the amount of ammonia inside the isolator is negligible, the elements can then be removed from the isolator.

The detected leaks must be sealed. The solution applied depends upon the leaks position. It may be :

- Apply special tight cello tape around the tubes.
- Install additional flexible plastic tubes, above existing connections.
- Apply silicon.

Reserves :

- Noroit engineers must gain full access to the ventilation network, in the very small laboratory. If this requirement is not fulfilled, some modifications will be done, but not in an optimal way.
- Safety work conditions must be fulfilled.
  - Especially, if engineers must sneak under the lift table, to reach the ventilation network installed at the rear or at each side of the equipment, the table must be mechanically locked and additional stands must be installed under the table to avoid an accidental fall.
  - The pipe connecting the isolator's exhaust to the outside of the laboratory must be tight to avoid ammonia leaks.
- If silicon has been applied onto the equipment, one night is needed to reach full drying.

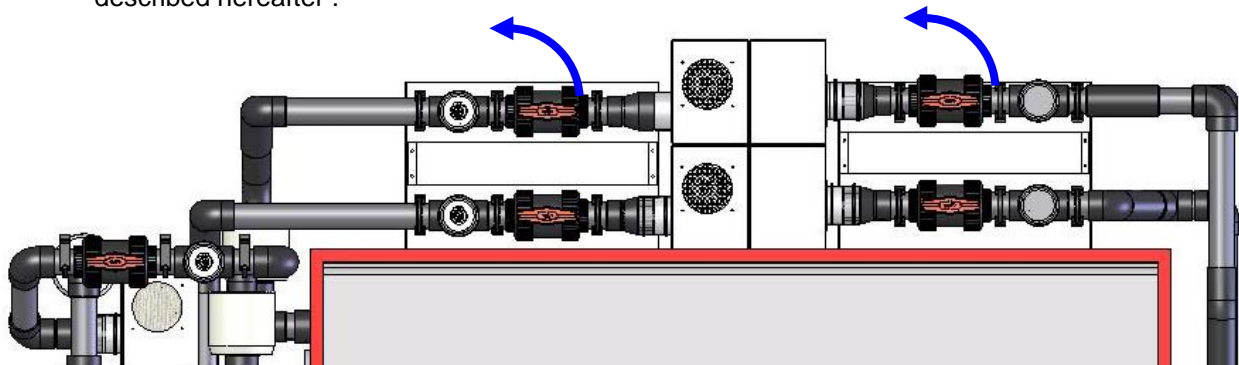
The qualitative test must be performed again, to check that the applied modifications have been effective, and as often as required, till there is not any leak left, and the quantitative test will pass.

Same procedure for both isolators.

### 1.2 Quantitative pressure test description :

The qualitative test must be performed prior to the quantitative test.

- The positive pressure inside the isolator is set around 100Pa, as displayed on the control panel.
- The valves, normally used for sterilization, are then simultaneously positioned as "closed", as described hereafter :



**Closed position – upper isolators**

- The fans are then switched off, using the buttons, on the control panel.
- The pressure value displayed is noted every minute.
- The test is successful if the displayed pressure is above 75 Pa, after 10 minutes.
- Same procedure for both isolators.

When the test is passed, the "50032" technical specifications must be filled by Noroit and approved by UAB.

One copy will be kept by Noroit, another one will be kept by UAB.

See Addendum for the 50032 spec.

### 1.3 Control of the air cleanliness classification : ISO 5 – Class 100.

The particle counter sensor must be installed inside the isolator : The sensor passes through a glove finger. The sealing is ensured by cable clamps.

The isolator is left running for at least 30 minutes. This delay is needed to flush the chamber from particles. The counting is then launched for one cubic feet.

Several counting are performed, till the isolator reaches the correct air cleanliness classification.

When the test is passed, the "50046" technical specifications must be filled by Noroit and approved by UAB. One copy will be kept by Noroit, another one will be kept by UAB.

The results are printed and stapled to the technical specification.

See Addendum for the 50046 spec.

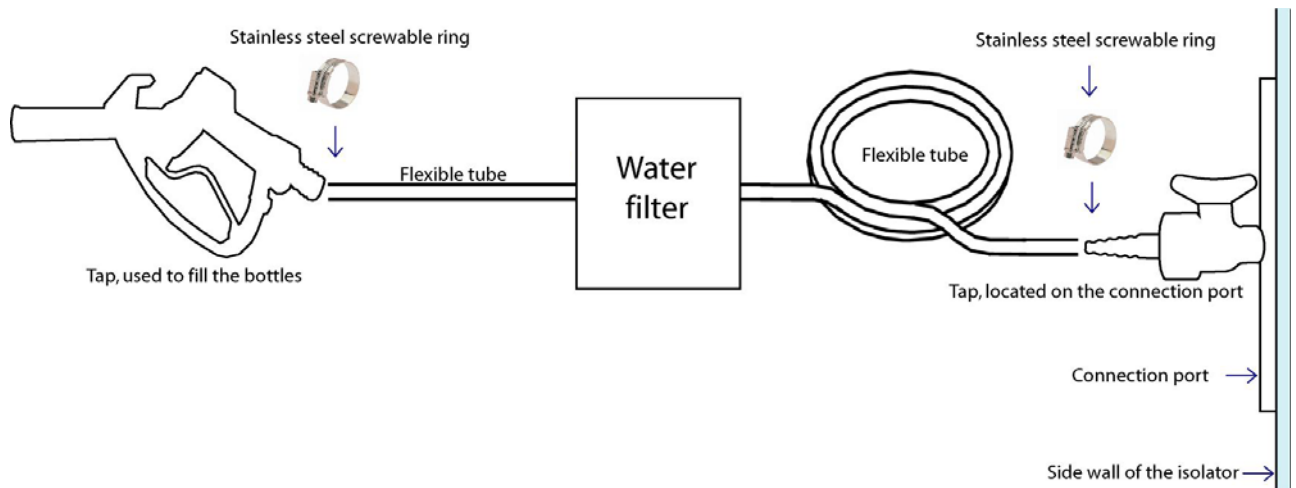


#### 1.4 Lift table maintenance :

- Oil leaks in the lift table hydraulic system.  
The washers have probably suffered from the moving of the whole equipment, in July.  
The leaks will be detected and repaired.  
The “50048” technical specifications must be filled by Noroit and approved by UAB.  
One copy will be kept by Noroit, another one will be kept by UAB.  
*See Addendum for the 50048 spec.*
- Punctual bending of the platform :  
The installation requirements of this kind of lift table specify that the floor must be extremely well adjusted. Especially, there should not be any gap between the 2 legs levels.  
We do believe that this is not 100% fulfilled in the laboratory, even if this is not clearly visible to the naked eye.  
However, the current functioning of the lift table, including this slight bending, has been accepted by UAB, (non compliance dynamic SAT report, corrective action, n° 2009-07-001, included in addendum).  
UAB may take in charge the ground levelling modification, in the laboratory, to avoid this punctual bending of the platform.

#### 1.5 Water tap installation :

The water tap must be connected to the water network, as described hereafter.  
The water tap is already installed onto the fluid port, inside the isolator.  
It still needs to be connected to the 0.1 µm hydrophilic polyvinylidene fluoride (PVDF) membrane water filter.  
The water filter must also be connected to the water distribution tap, as follow :



Tests will be performed to guarantee that :

- Water distribution is fulfilled.
- There is not any leak on the water network, inside the isolator.

When the test is passed, the “50047” technical specifications must be filled by Noroit and approved by UAB.  
One copy will be kept by Noroit, another one will be kept by UAB.  
*See Addendum for the 50047 spec.*

## 2/ EQUIPMENT CONTRACT (Consumables delivery and workforce)

The goal is to schedule the consumable parts replacement, to avoid the risk of using non sterile and unsafe equipments, due to parts ageing.

Consumable parts list, included in the offer :

**Proposal :** \_\_\_\_\_

Qty	Referen ce	Designation	Price Euros HT	Total cost HT
	A000009	50m <sup>3</sup> HEPA H13 Filter	220,00	0,00
3	A000216	Mini-filter used for the manometer and probe (threaded)	19,00	57,00
	A000043	Mini-filter used for the manometer and probe (fluted)	23,00	0,00
8	A000019	jersey with PVC coating sleeve	58,00	464,00
8	A000044	Shoulders circle ring	9,50	76,00
16	A000036	Wrists circle ring	5,25	84,00
8	A000357	Shoulders flat ring	18,00	144,00
	A000354	Pair of neoprene gloves- Size : 6 - width. : 0.45mm	63,00	0,00
6	A000314	Pair of neoprene gloves - Size : 7 - width. : 0.45mm	63,00	378,00
	A000355	Pair of neoprene gloves - Size : 8 - width. : 0.45mm	63,00	0,00
	A000356	Pair of neoprene gloves - Size : 9 - width. : 0.45mm	63,00	0,00
TOTAL, Euros				1203,00

**Equipment contract annual cost:**

**1203,00 Euros H.T.**

An additional visit, in case of failure, is also included. This visit will take place within a period of 48 hours following the customer phone call.

It includes free replacement of the defective consumables parts. However, in this case, the workforce and travel costs will be fully charged to the customer.

<b>SUMMARY</b>
----------------

**Servicing contract No. : 0811132 B**

**A/ Basis contract :**      1 visit & report      2460,00 **Euros H.T.**

**B/ Equipment contract :**      1203,00 **Euros H.T.**

<b>Type of contract selected :</b>	<b>YES</b>	<b>NO</b>
A option	<input type="checkbox"/>	<input type="checkbox"/>
B option	<input type="checkbox"/>	<input type="checkbox"/>

**Total cost (A + B) :**      **3663,00 Euros H.T.**

Between the undersigned :

The company      **NOROIT**  
                           **« Rezé Créatic »**  
                           **2 rue Robert Schuman**  
                           **44408 Rezé Cedex**  
                           **FRANCE**

and,

**Escuela Tecnica Superior de Ingenieria (ETSE)**  
**Universidad Autonoma de Barcelona**  
 Departamento de Engenharia Quimica  
 Campus de Bellaterra (Barcelona)

Represented by :

Sign  
 Please, indicate « For agreement » :

For NOROIT



NOROIT undertakes to perform the control of the equipment and the associated air filtering systems, with respect to the following general conditions, mentioned hereafter.

A copy of this contract must be kept by the customer, another copy shall be send back to NOROIT, duly dated and signed, together with the corresponding order.



**WARNING :**  
 NOROIT engineers will only perform tests and controls on decontaminated, pathogen-free, and toxic free equipments.

## GENERAL CONDITIONS

### **CONDITION #1 : CONTRACT GENERAL DEFINITION**

This contract involves servicing, technical assistance, and control of the equipments, as described above in this document.

### **CONDITION # 2 : WARRANTIES**

A standard visit is scheduled once a year.

Other visits : The control and servicing will take place within a period of 48 hours following a phone call. Limits are explained in the following condition.

### **CONDITION # 3 : LIMITS**

Parts replacements are not included in this contract, if they result from the following failures :

- Damages resulting from a bad use of the equipment, negligence, or malicious intent,
- Strikes, riots, storm,
- Fire, theft, water damages,
- Thunder, war,
- Mains supply over voltage or failure,
- Modifications of the equipment, (technical features added or removed) undertaken by the customer, without the authorisation and validation by NOROIT.
- Inappropriate use of the equipment
- Unintended use of the equipment,

And globally, every failure caused by major forces.

### **CONDITION # 4 : DETAILS OF IMPLEMENTATION**

NOROIT undertakes to service the equipments according to the rule book and with respect to European standard.

#### **4.1 SERVICING DATES :**

The standard servicing visit will be scheduled at least 2 weeks before, by the subscriber, in agreement with NOROIT.

NOROIT is not responsible for possible delays, due to strikes, accidents, war, etc...

#### **4.2 SERVICING PLACE**

Servicing will take place on the equipment's installation site. The customer will assure free access to the equipment during the time defined for servicing.

The standard servicing visit (once a year) will take place from Monday till Friday, from 8:00 till 18:00.

It may be possible to schedule different work time. They must be defined in agreement with NOROIT and will result in possible over cost.

#### **4.3 RESULTS**

A report will be issued after every visit. This report will list every results and comments.

On customer demand, NOROIT undertakes to give further information regarding the control results and comments.

A sticker will be positioned onto the equipment, indicating the date of control.

#### **4.4 CUSTOMER ATTENDING THE CONTROL**

The customer undertakes to indicate to NOROIT engineers every failure or malfunctioning, detected on the equipment.

The customer does not need to attend to the control procedure. However a signed agreement is required, on site.



**CONDITION # 5 : RESPONSABILITY**

NOROIT responsibility will be engaged in case of mistake or negligence from NOROIT engineers. The customer will then get compensation, with respect to the damages caused to the equipment.

**CONDITION # 6 : DATE OF START**

The contract will take effect from the sign agreement date.

**CONDITION # 7 : LENGHT**

The present conditions are defined for one year.

**CONDITION # 8 : CANCELLATION**

The customer and NOROIT may denounce the contract. The cancellation must be done via a registered mail, including the acknowledgment of receipt, at least 3 months before the scheduled end of contract.

The cancellation will not bring about any compensation.

In case of non fulfilment of the conditions defined in this contract, among them if the customer does not settle up the required sum, at current liabilities, NOROIT has the right to cancel the contract.

This procedure may take place 30 days after the customer is given notice to pay.

**CONDITION # 9 : MODIFICATIONS**

Following the customer demand, this contract may be amended.

However, every modification of this contract will result in an addendum form.

**CONDITION # 10 : SERVICING COSTS, NOT INCLUDED IN THIS CONTRACT**

Servicing or repairing caused by failures not listed in this contract will be charged to the customer, with respect to the servicing rate and travel costs.

**CONDITION # 11 : CLAIMS**

Execution and interpretation of the terms of this contract fulfills the French laws.

Controversy regarding this contract, if the customer and NOROIT does not find any amicable issue, will be submitted to the NANTES court, defined as the only court of competent jurisdiction.

**CONDITION # 12 : PAYMENT**

**12.1 DETAILS OF PAYMENT**

Payment will take place, on invoice reception, shortly after the sign agreement.

Exceptional additional visit : Payment will take place after each visit, on invoice reception.



**Noroit**

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2 rue Robert Schuman  
44408 Rezé Cedex, FRANCE

Tél. : 332.40.50.12.77

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contact@noroitlabo.com

[www.noroitlabo.com](http://www.noroitlabo.com)

**TECHNICAL SPECIFICATION**

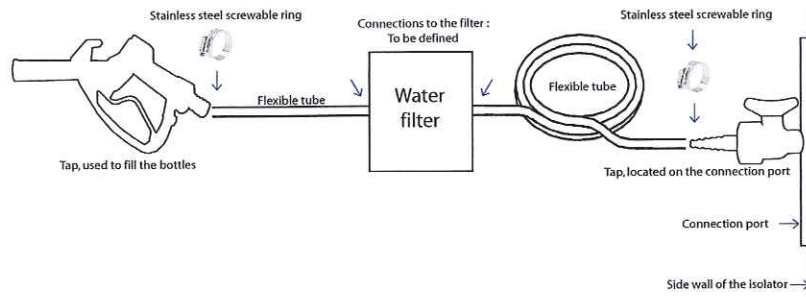
**50047 A**

**WATER NETWORK :  
WATER TAP-FILTER-FLEXIBLE PIPES  
INSTALLATION AND TEST**

**Control of the water tap, filter and flexible pipes inside the isolators :**

**OBJECTIVE**

1. Check that the water tap, filter, and flexible pipe is installed inside the isolators, as follow :



2. Check that there is not any water leak.

**PRE REQUIRED**

The required equipments must be available.

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
Visual inspection that the water network, inside the isolator, is correctly set.	Fulfil the above requirement.	See comments	C	13/03/2010 <i>[Signature]</i>
Visual inspection that water is not dripping from the network.	No drop.	Not applied	C	13/03/2010 <i>[Signature]</i>

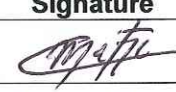


**Comments :**

The water filter is delivered inside a sterile plastic bag. In order to ensure sterility, it must be opened, later, in a sterile isolator. Noroit performed the connection between the flexible pipe and the tap, located on the fluid port. Further installation will be performed by

UAB. Tests will be performed by UAB. (after disinfection of the isolator)

**TEST STATUS**

<input checked="" type="checkbox"/> <b>ACCORDANCE</b>		<input type="checkbox"/> <b>NO ACCORDANCE</b>		See sheet(s) of non-compliance number :	
	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>	
Tested by :	G. NAHE	NOROIT	11/03/10		
check by :	E. PEIRO	ESA / UAB	11/03/10	Eusque Peiro	

\* C = Compliance / NC = Non Compliance

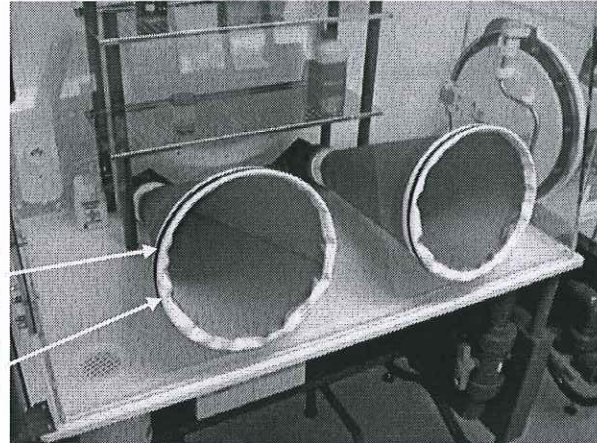


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## 2009 CONSUMABLES PARTS FARES

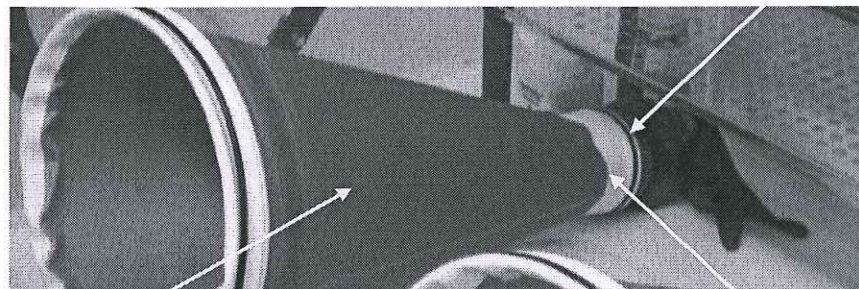
Validity : December 2009

GLOVES, SLEEVES, & RINGS



Shoulders circle ring

Shoulders flat ring



Wrists circle ring

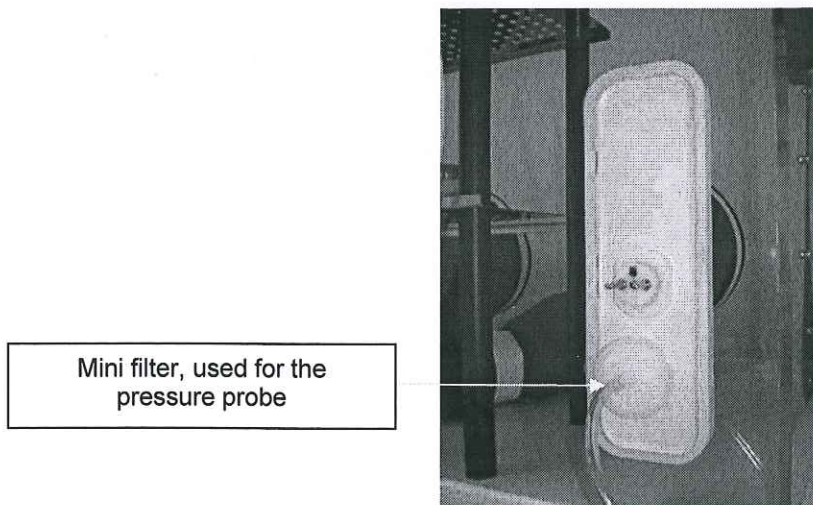
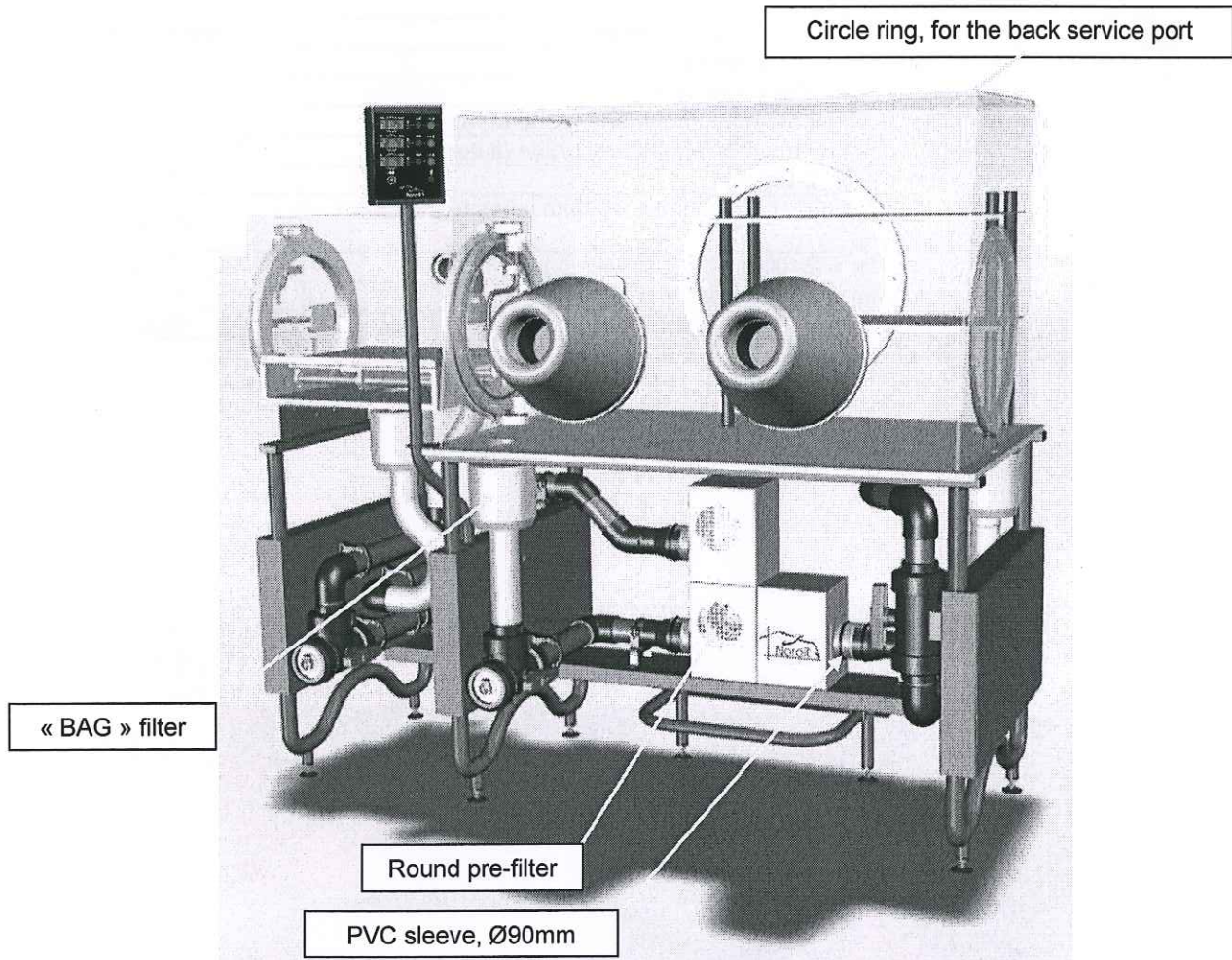
Jersey sleeve, with PVC coating

Wrist cylinder

Reference	Designation	Unit price
A000357	Shoulders flat ring	17.00
A000044	Shoulder circle ring	9.00
A000036	Wrist circle ring	5.00
A000019	Jersey sleeve, with PVC coating	55.00
A000120	Wrist cylinder	36.00
A000354	Pair of neoprene gloves – Size : 6 – Width. : 0.45mm	60.00
A000314	Pair of neoprene gloves – Size : 7 – Width. : 0.45mm	60.00
A000355	Pair of neoprene gloves – Size : 8 – Width. : 0.45mm	60.00
A000356	Pair of neoprene gloves – Size : 9 – Width. : 0.45mm	60.00



FILTERS AND RINGS



Reference	Designation	Unit priceHT
A000009	50m <sup>3</sup> BAG Filter(For isolators)	210.00
A000374	50m <sup>3</sup> BAG Filter (For containers)	72.00
A000216	Mini-filter used for the manometer and probe (threaded)	22.00
A000043	Mini-filter used for the manometer and probe (fluted)	22.00
T000003	Round pre-filter, Ø150 mm	3.00
A000213	PVC sleeve, Ø90mm (To connect Ø63mm tubes to the fan compartment)	22.00
T000002	Circle ring, for a Ø400mm back service port	12.00
T000004	Circle ring, for a Ø500mm back service port	14.00
T000005	Circle ring, for a Ø600mm back service port	18.00



## **11. FINAL            INSTALLATION            AND TESTING**

- **Lift table repair and testing**
- **Water network installation and testing**



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**TECHNICAL SPECIFICATION**

**50048 A**

**LIFT TABLE :**  
**LEAK DETECTION, REPAIR AND TEST**



**Repair the oil leak, in the lift table's hydraulic system, and test :**

**OBJECTIVE**

1. Detect the oil leak, in the hydraulic system.
2. Repair the leak.
3. Check that there is not any leak.

**PRE REQUIRED**

- Safety requirements must be fulfilled :
- The table must be mechanically locked.
  - Additional stands must be installed under the table to avoid an accidental fall.

TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
After having the leak repaired, move the table up and down several times.	No leak. Correct functioning	OK	C	10/03/2010 <i>[Signature]</i>
Leave the table for one night, and then perform a visual inspection of the ground, under the table.	No leak.	OK	C	<i>[Signature]</i>



**Comments :**

**TEST STATUS**

**ACCORDANCE**
                         
  **NO ACCORDANCE**

See sheet(s) of non-compliance number :

	Name	Company	Date	Signature
Tested by :	G. MAHE	NOROIT	10/03/10	<i>[Signature]</i>
check by :	E. PEIRO	ESA / UAB	12/03/10	<i>[Signature]</i>

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**TECHNICAL SPECIFICATION**

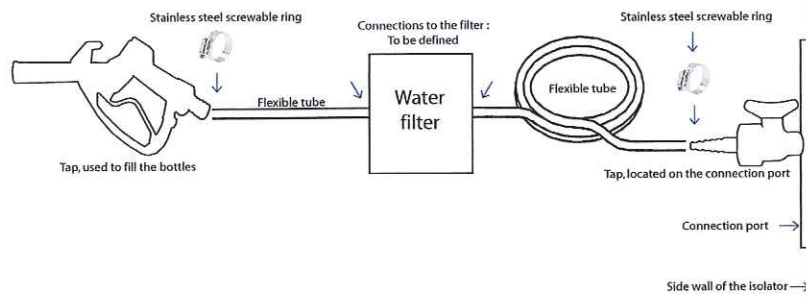
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WATER TAP-FILTER-FLEXIBLE PIPES  
INSTALLATION AND TEST**

**Control of the water tap, filter and flexible pipes inside the isolators :**

**OBJECTIVE**

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2. Check that there is not any water leak.

**PRE REQUIRED**

The required equipments must be available.

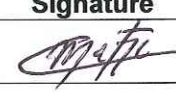
TEST PROCESS	RESULT EXPECTED	RESULT OBTAINED	C/NC*	DATE / SIGNATURE
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Visual inspection that water is not dripping from the network.	No drop.	Not applied	C	13/03/2010 <i>[Signature]</i>

**Comments :**

The water filter is delivered inside a sterile plastic bag. In order to ensure sterility, it must be opened, later, in a sterile isolator. Noroit performed the connection between the flexible pipe and the tap, located on the fluid port. Further installation will be performed by

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	<b>Name</b>	<b>Company</b>	<b>Date</b>	<b>Signature</b>	
Tested by :	G. NAHE	NOROIT	11/03/10		
check by :	E. PEIRO	ESA / UAB	11/03/10	Eusque Peiro	

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## 12. COMMENTS

### *MELiSSA Pilot Plant: CV detailed engineering datapackage*

#### *Comments*

##### **General comments**

A P&ID is missing, but I understand it has not been delivered by Noroit, hasn't it?

NOROIT indeed did not deliver a PID at the time the document was released. In fact, we are preparing in MPP our own PID already in VISIO and with the correct TAGS.

For the leak test , I would like to have a practical understanding of the leak test procedure: initially you planned to have a positive pressure of 100Pa, why do you later on go to 125 Pa? If you are loosing 25Pa over 10 minutes, how many % of your gaseous volume do you loose? Is it coherent with the leak "authorized" on other compartments, e.g HPC?

I propose to cover the procedure justification in the functional testing of CV.

We agree with your approach to justify during the functional tests. Regarding the comparison with the HPC, in fact as we cannot overpressurize the chamber we perform the test based on CO<sub>2</sub> decay, we were discussing this possibility with NOROIT but it was not their standard and we had not CO<sub>2</sub> measurement installed at that time. So either we perform some calculations or we can as well measure CO<sub>2</sub> decay once we will have this measurement in CV.