STANDARD OPERATING PROCEDURE

Title	SafeFAST Premuim Class II Microbiological Safety Cabinets
Short title	Safe FAST Premium ClassII

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1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the operation and maintenance of the SafeFAST Premium Class II microbiological safety cabinet.

2 Scope

This SOP applies to all users of the SafeFAST Premium Class II microbiological safety cabinet.

3 Abbreviations and definitions

Abbreviations and definitions included in alphabetical order

3.1 Abbreviations

BNITM	Bernhard Nocht Institute for Tropical Medicine
BSC II cabinet	Biosafety cabinet, safety class II
LAF	Laminar air flow
N/A	Not applicable
SOP	Standard Operating Procedure
VIR	Department of Virology

3.2 Definitions

SOP	A detailed, written instruction to archive uniformity of the performance of a specific function.

4 Responsibilities

Role/Title	Responsibilities/Tasks
Head of Laboratory	Release valid version of the SOP for use in the laboratory.
Designated senior laboratory staff	Take care of the regular review process for the SOP and supervise SOP and process specific trainings and the corresponding documentation.
All laboratory staff	Use and maintenance of the SafeFast Class II cabinet in accordance to this SOP and the user manual.

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5   General description

5.1   Principles

The SafeFAST Premium cabinet is designed to protect both, the material to be manipulated from contamination and the operator and environment from microbial contamination hazards.

The dusted, filtered and sterile air passing through the main HEPA filter ensures optimum airflow laminarity on the work surface, due to its even perforation and the frontal air barrier. The system is designed to create a protective barrier and prevent exchanges between the internal, potentially contaminated air, and the outside.

SafeFAST Premium cabinet is a Class II Biohazard cabinet, according to the definitions now adopted by all the main international standards suitable for the treatment of class CDC-2/3, DHSS-B2/B1 group 1,2,3 microorganisms as per D.L. 81/08 "Safety in the working environment" and wherever a product-personnel-environment cross-protection is required.

6   Device requirements

Installation area for the cabinet must fulfill the following requirements:

- Should be away from drafts and heat sources (such as radiators and ventilators), to ensure proper functioning of the cabinet.
- Install the cabinet in a well-ventilated room with a low degree of dust.
- Place the cabinet away from doors and windows. The door of the room should be in such position relative to the cabinet to prevent drafts.
- Place the cabinet in a place with little human traffic.
- Ensure that the required voltage and power is available before connecting the cabinet to the power supply. The room must have an earth connection.
- Make sure that the supporting table for the cabinet is placed on a leveled even floor and not on a slope.

6.1   Environmental requirements - temperature and humidity for the SafeFAST cabinet

Minimum temperature	+5 °C
Maximum temperature	+40 °C
Maximum humidity	80 % at +31 °C, linear drop in relative humidity down to 50 % at +40 °C

7   Material and equipment

7.1   General

- Waste stand and disposal bag
- Waste bottle

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7.2   Maintenance

- Soap based lab cleaner
- 70 % ethanol

Note: Quaternary ammonium-based cleaners are also suitable for cleaning

7.3   Storage

N/A

8   Safety

- Make sure to not use chlorine-containing disinfectants which may damage stainless steel surfaces.
- Do not use disinfectants with an alcohol content higher than 70 %, as these may cause damage to plastic components after extended use.
- Treat all materials in the work area as potentially contaminated with pathogenic material, the appropriate personal protective equipment must be worn when working in the cabinet.

9   Procedural description

9.1   Start-up process

9.1.1   Functional check

Every time the SafeFAST Premium cabinet is turned on, the cabinet will automatically perform the start-up and check for the laminar flow and the exhaust velocity to reach the pre-set values (required time (about 40 seconds)).

The SafeFAST Premium cabinet is provided with an automatic regulation system to keep the airflow speed in the work chamber and the recycling air/extracted air ratio constant during operation.

A functionally check must additionally be performed by a service technician during installation and thereafter during the annual service.

9.1.2   Calibration

Must be performed by a service technician during installation and thereafter during the annual service.

9.1.3   Validation

Must be performed by a service technician during installation and thereafter during the annual service.

9.2   Operation

9.2.1   Principles

The working principle of the SafeFAST Premium Biohazard cabinet is described as follows:

Pressurized air pushed into the plenum of the main motor-fan passes through the absolute filter and then downwards, in a laminar flow, into the (A) working chamber. From here, through the perforated surface, having mixed with the (B) external air which enters the cabinet from the front opening, it is sucked into the intake up channel situated at the rear of the work chamber (C). Part of the air is exhausted (D) through the exhaust HEPA filter. This extracted air lets air come in from the

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outside (front barrier) ensuring the protection of the operator/environment from hazardous material manipulated in the work area. The flow of air through the cabinet.
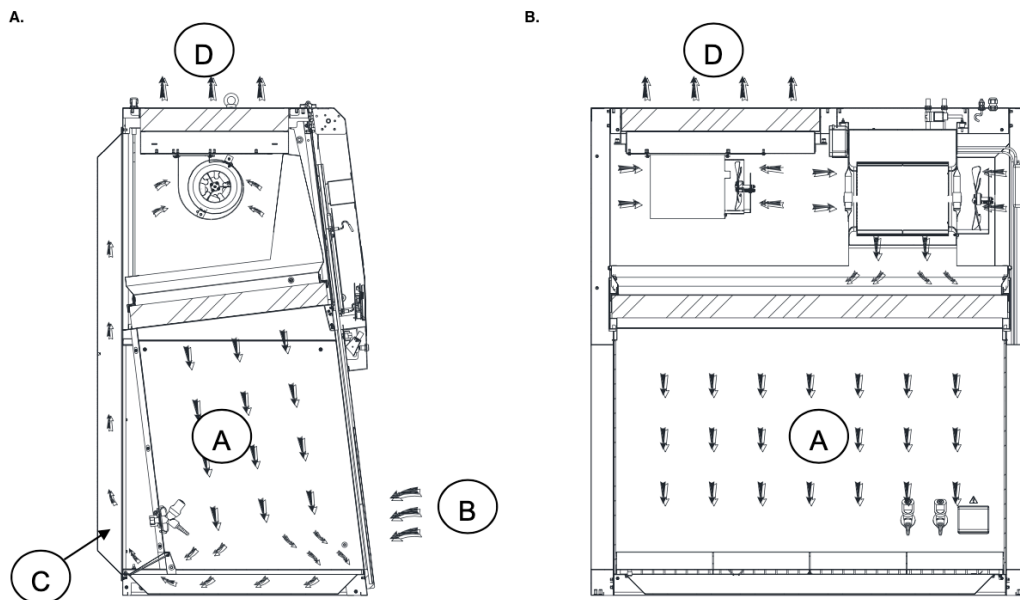
Figure 1 Side (A.) and front (B.) view of the cabinet, illustrating airflow.

9.2.2   System and performance controls

The SafeFAST Premium cabinet is provided with an automatic regulation system to keep the airflow speed in the work chamber and the recycling air/extracted air ratio constant even with the progressive clogging of the two HEPA filters up to the maximum pressure supported by the motor-fan.

The soft-touch control panel is microprocessor-controlled with a display showing all relevant data with regard to the operating functions, the different alarms and the error messages.

The perforated work surface creates optimal airflow laminarity at working level, while the front longitudinal slots create a protective air barrier.

The vertically sliding safety glass sash is electrically operated. When the cabinet is running the work opening must be 160mm; any moving of the glass activates an audible and visual alarm, which cannot be silenced according to the EN 12469 standard.

When the cabinet is off the glass can be either opened up to the maximum opening or closed completely.

9.2.3   Symbols of the control panel
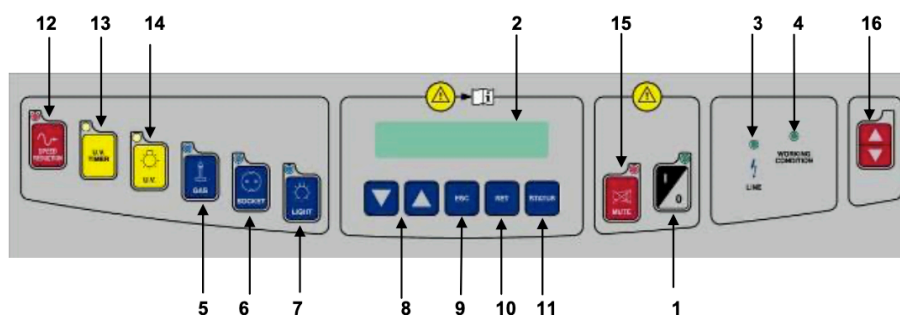
Figure 2 Control panel of the SafeFAST cabinet.

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1	Main Switch "0" "I"	"0" position, the green light of the mains voltage is on **(3)** In this position the operator can activate only the fluorescent light **(7)**, the U.V. lamp **(14)** and the power outlet **(6)** (with plug installed) "I" the password to enter is requested. When the password is typed in (press arrow-up key (▲) 5 times, arrow-down key (▼) 4 times and press SET) the green led of the switch lights up and the cabinet starts operating. "CHECK PANEL" then "STAND-BY" appears on the display. The LCD shows the required time (about 40 seconds) for the laminar flow and the exhaust velocity to reach the pre-set values. An audible alarm will sound during this stand-by period, **alerting the operator not to start working yet.** Once the alarm stops, "STAND-BY" message will disappear from the display, **the cabinet is ready for use.** **NOTE: It is advisable to wait 5 minutes before starting work**
2	Display	LCD display composed of 2 lines of 20 characters each showing the operating parameters and alarms.
3	Line	The green mains light switches on if the unit is connected to the mains and the line is live.
4	Working Condition	The green LED lights up when the ventilation works correctly.
5	Gas	This activates the control for opening/closing the gas electro valve; when enabled, the display shows "GAS ON". It operates only when the cabinet is running to prevent possible over-heating and risks of damaging the HEPA filter.
6	Socket	This supplies voltage; when enabled, the display shows "POWER ON".
7	Light	This switches on the internal light; when enabled, the display shows "Light on".
8	Up/Down Arrows	Use the arrow keys to scroll the menu, to program changing parameters and to put in the password.
9	Esc	ESC key deletes the operation of data input and goes back to the starting condition.
10	Set	SET key lets you enter the different functions or confirm the data input going back to the upper level.

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11	Status	If pressed in sequence, the following data will appear on the display: **External Temperature:** Shows the temperature outside of the cabinet; the LCD will display (for example) "EXT. TEMPERATURE = 27 °C" **Internal Temperature:** Shows the internal temperature of the cabinet work area; the LCD will display (for example) "INT. TEMPERATURE = 30 °C". **U.V. Lamp Residual Lifetime:** Shows the operating time of the U.V. lamp pre-set by the user with the appropriate keys. **Residual lifetime of filters:** it is the operation time of the filters installed in the cabinet that can be programmed by the user. **LAF Power**: it is shown indirectly by the power supply voltage of the main motor, expressed as percentage of max. load voltage displayed also in proportion by a bar. **EXH Power:** it is shown indirectly by the power supply voltage of the exhaust motor, expressed as percentage of max. load voltage displayed also in proportion by a bar. **Operating Time:** Shows the operating time of the cabinet from the moment when the main switch is positioned on "I"
12	Speed Reduction	The "SPEED REDUCTION" function can be enabled only with the main switch in position "I". Only the power supply (3) can be operating.
13	U.V. timer	This concerns the yellow key for the timed management of the U.V. lamp (with timer). When the front sash window is completely down, by pushing the relevant key, you are requested to set the time. The timer resolution is 1 minute and the maximum time is 180 minutes (3 hours).
14	U.V.	Yellow key to switch on UV lamp with non-programmable timer. This supplies the U.V. lamp in "manual" mode; when enabled, the display shows "U.V. on". The U.V. lamp switches on only if the cabinet is off, the lighting of the cabinet is off and the front sash window is completely closed. After 180 minutes the U.V. lamp switches off automatically.
15	Mute	The red alarm LED lights up when an alarm condition occurs, which is shown also by the message appearing on the LCD. Pushing the MUTE button will stop the alarm sounding
16	Up/Down arrows	Red safety button only in cabinets fitted with electrically operated vertically sliding sash

9.2.4 Operating Procedures

Before performing any work in the cabinet, the following must be verified:

- The cabinet is connected to the mains/power supply.
- All the alarm lights are off.
- Work area inside the cabinet is free from materials used during the previous session.
- The cabinet has been cleaned and sterilized in case of change in the nature of work to be performed.

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9.2.4.1 Switching on the cabinet
1. Turn the light on by pushing the blue button **(7).**
2. Make sure that the sash window is in the work standard position.
3. Press the main key **I/0 (1)** and enter the password (**"up-arrow"** for 5 times, **"down-arrow"** for 4 times, and press **"SET".**
4. After 40 seconds of stand-by, the cabinet is ready for work. "STAND-BY" disappears from the screen and the LAF and protection barrier velocities are displayed.
5. Wait for 5 minutes before starting work.
6. During this period of time, introduce into the internal work zone of the cabinet only the materials which are indispensable for the job at hand.

9.2.4.2 Working in the cabinet
- All movements made under the laminar air-flow cabinet should be parallel to the work surface. Work in the middle of the table to avoid upstream contamination.

9.2.4.3 Switching off the cabinet
1. Remove material (equipment, consumables, samples and waste) for the working chamber.
2. Clean the work surface and the inside walls of the chamber, as described in 11.1.1.
3. Slide the sash window completely down and switch on the germicide lamp by pushing the "U.V." yellow key **(14).**

10 Waste management
- Waste material generated during work performed inside the cabinet must be treated as infectious and must be disposed according to the local and national regulations for biological hazardous material.
- The HEPA filters replaced during annual maintenance of the cabinet must be treated as biologically toxic, local and national regulations must be followed when disposing the old filters.

11 Maintenance
11.1 Internal
11.1.1 Daily Cleaning
- To clean the outside of the cabinet, use a damp soft cloth soaked in soapy water to wipe the metallic surfaces. Switch the cabinet off and disconnect the feeding cable.
- Clean the inside working area with an alcohol-based disinfectant (≤ 70 % ethanol). Do not spray directly onto the work surface. Use paper towel or cloth.
- Do NOT use chlorine-based cleaners such as bleach to clean the cabinet, as this is corrosive to the steel and stainless steel and will result in irreparable damage to the cabinet structure.
- If pathogenic material has been spilled during the work session, sterilize the work surface, then remove it using the small handles mounted on the sides. Sterilize the spilled materials contained in the collection basin located under the table and wipe up all spilled material using paper towel.

11.2 External

11.2.1 Sterilization/fumigation

The following must be performed by a service technician during the annual servicing of the cabinet:

- Sterilization/fumigation of the cabinet
- Replacement of the HEPA filters

12 Troubleshooting

12.1 Troubleshooting

Probable causes of malfunctions are listed in the table below. In the event of malfunctions requiring the replacement of parts, contact the service technician.

Probable causes of malfunction

PROBLEM	CAUSE	REMEDY
Cabinet does not work	– the electricity supply has been cut off at the mains – Electronic board out of order – Blown fuse(s)	– check the voltage input to the cabinet – Replace PCB – Replace fuses
Alarm: "HEPA filters check"	Main HEPA filter clogged	Replace HEPA filter
Alarm: "low barrier velocity"	Double-fan cabinet: the exhaust motor-fan does not work	Check the exhaust motor-fan Check F6 fuse on the power card Check that the exhaust duct is not clogged
	Single-fan cabinet	Check that the exhaust duct is not clogged
"minimum LAF alarm". **[Possible contamination of the product but protection of the environment]**	HEPA filters clogged .	Replace HEPA filters.
	The main motor-fan does not work	Check the terminal voltage of the power card of the main motor-fan Check F7 fuse on the power card Replace the power card Replace the microprocessor card
"Black-out " Alarm **(probable exchange of air between the work chamber and the outside and possible contamination of the environment)**	Blackout	Check the feeding cable, the connection plug/socket, the power supply line Press "Mute" [15] key to silence the alarm
Alarm "Sensors failure"	Failure of sensor XX	Replace XX sensor.
Alarm: "No encoder input LAF"	No signal from LAF flow sensor	Replace the LAF sensor
Alarm: "No encoder input EXH"	No signal from Exhaust flow sensor that is out of order	Replace exhaust sensor

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12.2 Alarms or error messages

List of alarms and error messages and description of causes

ALARM OR ERROR MESSAGE	DESCRIPTION
Min. LAF Alarm	Airflow speed in the work chamber under minimum threshold value
Min. BARRIER Alarm	Insufficient air suction from the front aperture, thus air speed in the exhaust channel under minimum threshold value
LAF controller fail	Too fast and uncontrollable main motor-fan (LAF)
No encoder input LAF	No input from the fan anemometer installed on the LAF main motor-fan
No encoder input EXH	No input from the fan anemometer installed in the exhaust duct
Max LAF Alarm	Airflow speed in the work chamber over maximum threshold value
Position the window	The front window is not closed correctlly
UV Lifetime over	Residual lifetime of the UV lamp expired
Sensors failures	Failure to one of the sensors. Press "MUTE" key and the correspondent sensor is displayed
BLACK-OUT	Warning of black-out when the cabinet is working Press "MUTE" to stop the alarm
HEPA Filters Check	Possible clogging of absolute (HEPA) filters
Exhaust Duct Check	Possible clogging of the exhaust duct
Position the window	The sash window is not in the correct position
F1 (2, 3, 4, 5) lifetime over	Filter 1 (2, 3, 4, 5) residual lifetime is over
ATTENTION DANGER Reduced airflow. DO NOT WORK	Warning to pay attention when the speed reduction is activated (only for keyboards with "SPEED REDUCTION" key)
CHECK THE GLASS	The view-screen has not moved properly Check there are not obstacles below the screen. In case the screen is blocked by

13 References

D.L. 81/08 "Safety in the working environment":
https://osha.europa.eu/en/publications/safety-and-health-micro-and-small-enterprises-eu-policy-practice-description-good

14 Associated Documents

14.1 Tools associated with this SOP

BS Cabinet_maintenance_chart

14.2 Other documents associated with this SOP

Operating and maintenance manual SafeFAST Premium

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15 Document History

Review date	Version number	Brief description of changes
N/A	V01	First release