s@femate series cyto

Your total safety solution

BIOAIR®
a EuroClone® Division

MANUFACTURED ACCORDING TO DIN 12980

IN BAG OUT

Cytostatic drugs handling Cabinets (as per DIN 12980:2005-06)

s@fe**mate** *series*
cyto

Your total safety solution

Cytostatic drugs are therapeutic agents intended for, but not limited to, the treatment of cancer. These drugs are known to be highly toxic to cells, mainly through their action on cell reproduction. Many have proved to be carcinogens, mutagens or teratogens.

Cytostatic drugs are increasingly being used in a variety of healthcare settings, laboratories and veterinary clinics for the treatment of cancer and other medical conditions such as rheumatoid arthritis, multiple sclerosis and auto-immune disorders.

Health effects attributed to exposure to occupational cytostatic drugs can be very serious.

Research shows that where a high standard of risk control is in place, threats to healthcare are reduced.

However, no exposure limits are set for cytotoxic drugs. Medical opinion is such that even low-level exposure to cytostatic drugs should be avoided as much as possible. Research has shown that the implementation of suitable safety precautions reduces the incidence of adverse health effects [1].

BioAir cytostatic drugs preparation Cabinet s@fe**mate** *cyto* is manufactured and tested in accordance with DIN12980: 2005 and EN 12469:2000 standards and provides the laboratory technician with the maximum level of safety against inhalation of aerosols generated during the reconstitution protocols.

MAIN SPECIFICATIONS

Other than the two classic HEPA H14 filters needed for the filtration of exhausted air and downflow recirculating unidirectional airflow, a tertiary filtration stage HEPA H14 (with bag-in, bag-out filter changing protocol ensuring a safety level in excess of the one obtained with the Ohlmeyer procedure [2]) is located underneath the work surface in order to provide, by filtering 100% of the recirculated airflow, the required safety for the maintenance personnel when removing this stage of filtration for substitution.

Four levels of safety are therefore provided:

1. Safety for the operator, (extremely high retention factor) identical to the one provided by a Biological Safety Cabinet.
2. Safety for the environment (double HEPA H14 filtration stage in the exhaust flow).
3. Safety for the product and between products (much better than class 100 in the work area thanks to the double HEPA H14 filtration stage in the recirculated flow).
4. Safety for the engineers when changing the tertiary filter stage (patented bag-in bag-out procedure).

Technical specifications

- Microprocessor controlled motor blower, with volumetric sensor for exhausted air flow monitoring
- State of the art Microprocessor control system offering:
  - ✓ Large screen monitor.
  - ✓ Automatic control of preset airflow volumes.
  - ✓ Sliding sash window with smart control and “yzy” air-tight movement.
  - ✓ Permanent monitoring of HEPA filters life span.
  - ✓ Permanent display of working conditions.
  - ✓ Highest air flow stability both in case of transitional disturbances or progressive filter clogging.
  - ✓ Semi-automatic fumigation cycle (EN12297 tested and certified).
  - ✓ Continuous monitoring of front barrier air flow for the highest operator safety.
  - ✓ Low barrier alarm.
  - ✓ Power failure alarm.
- Volt-free contact for remote monitoring of exhaust fan or other functions related to cabinet status (on/off).
- Automatic reset of initial conditions in case of power failure.
- Shipped in two separated boxes (base and cabinet) for the easiest transportation and on-site installation.
- Prepared for installation of internal IP65 PC monitor (optional).

These last generation Cytostatic drug handling Cabinets have been manufactured according with the most stringent safety standards for this category of Safety Cabinets (DIN12980, EN12469).

The internal design, the air flow aerodynamics and monitoring, the built-in safety devices, the exclusive patented "bag-in, bag-out" filter changing protocol and the very accurate manufacturing guarantees the highest performances at the most stringent safety levels, as specified by DIN 12980 and EN12469 standard and have been certified by the most prestigious European certification body for Safety Cabinets.

Certified intrinsic safety, combined with impressively competitive prices, gives the end user a state of the art cabinet accessible to every budget, that only experienced European design and accurate quality manufacturing, can provide.

PATENTED ISOLATION CONTINUITY · PATENTED ISOLATION CONTINUITY ·
IN
BAG
OUT

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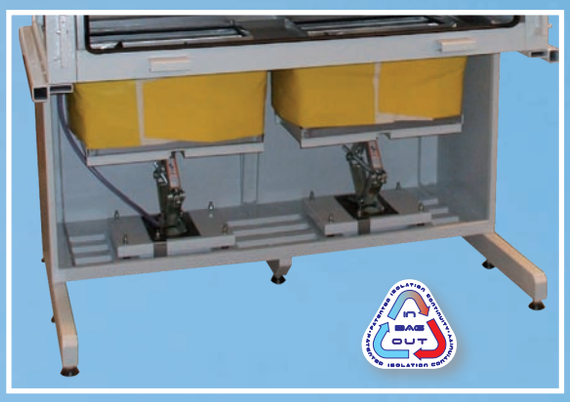
Mechanical and functional specifications

- Sloped front design for the highest operational comfort. Sloped back side of the working chamber for the best down flow distribution (cabinet carcass EN12298 tested and certified for air tightness).
- Utilities inlets from the top of the cabinet.
- AISI 304 Stainless Steel internal surfaces with 2B finishing (including spillage tray). Solid work surface (2 sections) and special designed front grill.
- Electrically operated sliding multilayer 6 mm safety glass window with "yzy" air tight movement (the front window is also hinged for the easiest cleaning procedures of internal glass surface).
- Comfortable 200 mm front opening.
- Easy to install retrofit options through lateral sides.
- Three stages H14 High Efficiency Particulate Air filters with 99.999% efficiency on 0,3 μ particles (most penetrating particle size) (EN1822-1 and EN 13091:1999 tested and certified).
- Filter change and maintenance from the front of the cabinet for all stage of filters.
- Bag-in bag-out tertiary filter stage changing technology (avoiding rupture of isolation continuity of the work area during filter changing; safety level in excess of the one obtained with the Ohlmeyer procedure [2].
- Exhaust transitions easily installable.
- Key operated. The key can be removed when the unit is in SAFE mode, in order to avoid unwanted operation. In case of power failure, the cabinet is re-set to original working conditions.
- Self calibration cycle performed at cabinet warm-up.
- Visual display of SAFE conditions. Pre-warning before actual alarm conditions are reached (visual and acoustic alarms).
- Soft touch control with keys for standard service utilities.
- Interconnected UV and fluorescent lights.
- Exhaust and recirculating flow rates ensure 25 air changes/min in the working area (30%, 70% split).
- Front barrier air speed ≥ 0.5mt/sec.
- Aperture protection Factor (Apf) ≥ 1.5 x 10^5 (retention efficiency).
- Cleanability Index "C" grade. (EN 12296 tested and certified).
- Light intensity on work surface > 1200 lux.
- Noise level ≤ 55dB(A) (ISO 11201, ISO 4871 and ISO EN 3744 tested and certified).
- Work surface displacement (vibration) <0.005mm RMS between 20Hz and 20,000Hz (ISO 5349 tested and certified).
- 220/240V, 50Hz power supply.
- Max power (for each power point) 3Amps.
- CE certification according to Machinery Directive 89/392/ EEC, 91/368/EEC, 93/44/EEC 93/68/EEC.



- The patented Bag-in, Bag-out filter changing technique with continuously hermetic separation between contaminated areas and the external environment using third stage of filtration (with no need to be removed from the inside of the work chamber of the cabinet) ensures a safety level in excess of the one obtained with the Ohlmeyer procedure [2].
- The engineer is always working from external, not contaminated environment, and he will never be in physical contact with contaminated materials or areas with potential high risk of contamination.

- High resolution large digital display.
- Permanent monitoring of HEPA filters life span.
- Alarms. Multilevel alarms, with redundancy functions.
- Permanent display of working conditions.
- Continuous monitoring of front barrier air flow for the highest operator safety.

- AISI 304 Stainless Steel internal surfaces with 2B finishing (including spillage tray). Solid work surface and special designed front grill.
- Cleanability Index "C" grade. (EN 12296 tested and certified).
- Light intensity on work surface ≥ 1200 lux.

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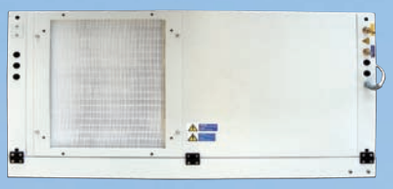
Front



Top

Side

Model

	s@femate *cyto* 0.9	s@femate *cyto* 1.2	s@femate *cyto* 1.8
Work chamber (wxdxh) mm	924 x 600 x 700	1230 x 600 x 700	1840 x 600 x 700
Overall (wxdxh) mm (*)	1074 x 840 x 2220	1380 x 840 x 2220	1990 x 840 x 2220
Front opening height mm	195	195	195
Weight Kg	280	340	450
Power supply	220/240 V - 50 Hz	220/240 V - 50 Hz	220/240 V - 50 Hz
Power W	350	400	750
Noise Level dB(A)	< 55	< 55	< 57
Lighting lux	> 1200	> 1200	> 1200

* Shipped in two boxes (base and cabinet)

How to order	
Cytotoxic Drug Handling Cabinets	
LY10000	S@femate Cyto 0.9 floor standing
LY20000	S@femate Cyto 1.2 floor standing
LY20800	S@femate Cyto 1.2 ABC floor standing
LY40000	S@femate Cyto 1.8 floor standing
LY40800	S@femate Cyto 1.8 ABC floor standing
UV	
AKC0001	Mobile UV light kit
Please enquire about the many option and accessories available.	

Installed standard utilities:
- 1 Vacuum tap.
- 2 Electrical socket (Schuko).
- Power failure alarm.
- Automatic recovery of initial conditions when mains return.

References
[1] Handling Cytotoxic drugs in the workplace Victorian Workcover Authority Melbourne Vic Australia (2003)
[2] M. Ohlmeyer, W. Strolz: Schwebstoff-Filteranlagen für die Abluft aus kerntechnischen Einrichtungen. Kernetchnik 15 (1973) Nr. 9, 416 - 423

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