LAB EQUIPMENT

Euro Clone®
serving science through innovation

BIOAIR®

safemate series cyto

Your total safety solution

Cytostatic drugs handling Cabinets
(Certified according to DIN 12980:2005-06 / EN 12469:2000)

- *Protect the operator*
- *Protect the environment*
- *Protect the product*
- *Protect the maintenance engineer*

IN BAG OUT
PATENTED ISOLATION CONTINUITY

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@femate Cyto is manufactured and certified 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.

These last generation Cytostatic drug handling Cabinets have been manufactured according to the most stringent safety standards for this category of Safety Cabinets and are certified according to DIN12980 and EN12469 by TÜV. 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.

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MAIN SPECIFICATIONS

Safety for the operator and the environment

(Three HEPA H14 filters, Certified intrinsic safety)

Operator protection is obtained thanks to the excellent containment efficiency of the front air barrier and the double filtration of the air discharged in the environment.

Safety for the product and the patient

(ISO5 = Class 100 inside, the cabinet work area)

The sterility of the drugs is essential for the safety of the patient.

Safety for the engineers

(Patented Bag-in/bag-out filter replacement system)

An important safety element is the third HEPA H14 filters stage placed underneath the work surface. Aerosols generated inside the work area are captured by the third stage filters preventing cytotoxic compounds to contaminate the interior of the cabinet.
Replacement of the third stage filters thanks to the patented "bag-in/bag-out" system is obtained without any risk of exposure to dangerous compounds both for the workers and the environment.
The downflow and exhaust filters further process the air coming from the third stage filters.
This filtration system exceeds the required ISO5 = Class 100 air cleanliness for the preparation of paranteral drugs and also the safety of the environment thanks to the three levels filtration of the recirculated air.

References

[1] Handling Cytotoxic drugs in the workplace Victorian Workcover Authority Melbourne Vic Australia (2003)

TECHNICAL SPECIFICATIONS

Safe and easy to use

- Solid work surface divided in sectors.
- Comfortable 195 mm front opening and special designed front grill ensures a constant front air barrier (air speed ≥ 0.5mt/sec).
- Retention efficiency: (Apf) ≥ 1.5 x 10^5 (Aperture protection Factor EN 12469)
- Sloped front design for the highest operational comfort and maximum work area visibility.
- Light intensity > 1200 lux.
- Work surface displacement (vibration) <0.005mm RMS between 20Hz and 20,000Hz (ISO 5349 tested and certified).
- Noise level ≤ 55dB(A) (ISO 11201, ISO 4871 and ISO EN 3744 tested and certified).
- Back wall installed IP65 PC monitor (option).

Safe and efficient filtration and ventilation system

- Three stages HEPA H14 High Efficiency Particulate Air filters with 99.995% efficiency on 0,1-0,3 µm particles (Most Penetrating Particle Size) (EN1822-1 and EN 13091:1999 tested and certified) ensures ISO 5 air cleanliness (according to ISO 14644-1) or Class 100 (according to FED STD 209E) mandatory to guarantee product sterility and patient health.
- Sloped back side of the working chamber for the best down flow distribution.
- Exhaust and recirculating flow rates ensure 25 air changes/min in the working area (30% exhaust, 70% recirculation split).
- Exhaust transitions easily installable.

In case of power failure, the cabinet is reset to original working conditions.

Easy and safe maintenance

• 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 is never in physical contact with contaminated materials or areas with potential high risk of contamination.

The Internationally Patented Bag-in/Bag-out filter changing technique (Patent IT N° 1.387.496 dated 13.4.2011; EU N° 09156281.9-1253 dated 26.3.2009) avoids rupture of isolation continuity of the work chamber during filter changing procedure ensuring hermetic separation between contaminated areas and the external environment.

References

[2] M. Ohlmeyer, W. Strolz: Schwebstoff-Filteranlagen für die Abluft aus kerntechnischen Einrichtungen. Kernetchnik 15 (1973) Nr. 9, 416 - 423

Continuous monitoring

The cabinet performance is constantly monitored through a sophisticated microprocessor.
Any malfunctions are promptly signalled to the operator through audible and visual alarms.

- State of the art Microprocessor control system offering:
  - LCD monitor
  - Automatic control of preset airflow volumes
  - Sliding sash window with smart control and “yzy” air/aerosol-tight movement
  - Permanent monitoring of HEPA filters life span
  - Permanent display of working conditions
  - 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.
- 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.
- Multilevel alarms, with redundancy functions.

Mechanical and functional specifications

Sturdy and reliable construction.
The robust metal work and the quality of the material ensure reliability and a long work life.

• Shipped in two separated boxes (base and cabinet) for the easiest and safest transportation and on-site installation.

• AISI 304 Stainless Steel internal surfaces with 2B finishing (including spillage tray).

• Solid worksurface and special designed front grill. Electrically operated vertical sliding sash (multilayer 6 mm safety glass) with "yzy" movement that ensures maximum air tightness when in working position, by pressing the glass against the sealing gasket. The sliding sash is also hinged to allow easy cleaning procedures of the internal glass surface (swing-out feature).

• Cleanability Index "C" grade. (EN 12296 tested and certified).

• Utilities inlets from the top of the cabinet.

• 230V-50Hz or 220-230V-60Hz.

CE certification according to Machinery Directive 89/392/ EEC, 91/368/EEC, 93/44/EEC 93/68/EEC.

Technical Features

	S@femate Cyto 0.9	S@femate Cyto 1.2	S@femate Cyto 1.8
Work chamber dimensions (WxDxH) (mm)	924 x 600 x 700	1230 x 600 x 700	1830 x 600 x 700
Overall dimensions (WxDxH) (mm)	1074 x 840 x 2220	1380 x 840 x 2220	1990 x 840 x 2220
Work access opening (mm)	195	195	195
Weight (kg)	310	340	450
Power supply	230V/50Hz or 220-230V/60Hz	230V/50Hz or 220-230V/60Hz	230V/50Hz or 220-230V/60Hz
Noise Level	≤55dB (A)	≤55 dB (A)	≤57 dB (A)
Lighting	≥1200 lux	≥1200 lux	≥1200 lux

EuroClone S.p.A. reserves the right to change product specifications without prior notice

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EuroClone S.p.A. has a Quality System certified in compliance with UNI EN ISO 9001:2008 and NF EN ISO 13485:2004

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