DATASHEET

Safemate Cyto
Cytotoxic drugs handling cabinet

Biosafety Cabinet for the preparation of Chemioterapic
Antitumoral drugs

- Designed according to DIN12980 and EN12469:2000
- State of the art microprocessor control system.
- Large digital display, high resolution
- Air and aerosol-tight sliding sash, electrically operated by finger touch
- Alarms for low air flow and wrong front window position
- Sloped front and back wall for the most comfortable access
- Front access for tertiary filter stage maintenance and service
- Bag-in bag-out tertiary filter stage changing technology (avoiding rupture of isolation continuity of the work area during filter changing according to KTA 3601 Lüftungstechnische Anlagen in Kernkraftwerken)
- Easy retrofit options

Cytotoxic 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.
Cytotoxic 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 cytotoxic drugs can be very serious.
Research shows that where a high standard of risk control is in place, threats to healthcare are reduced.
No exposure limits are set for cytotoxic drugs. Medical opinion is such that even low-level exposure to cytotoxic 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.

BioAir cytotoxic drugs preparation Cabinet **S@femate Cyto** has been designed and built according to DIN12980 and EN12469:2000 standards and provides the laboratory technician with the maximum level of safety against inhalation of aerosols generated during the reconstitution protocols.

MAIN SPECIFICATIONS

These last generation Cytotoxic drug handling Cabinets have been certified 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 and the very accurate manufacturing, guarantees the highest performances at the most stringent safety levels, as specified by DIN 12980 and EN12469.

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.

Other than the two classic H14 filters needed for the filtration of exhausted air and downflow recirculating unidirectional airflow, a tertiary filtration stage (with bag-in bag-out filter changing protocol according to KTA 3601 Lüftungstechnische Anlagen in Kernkraftwerken) 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 Aperture protection factor) identical to the one provided by a Biological Safety Cabinet
2. Safety for the environment (double H14 filtration stage in the exhaust)
3. Safety for the product and between products (class 100 in the work area)
4. Safety for the engineers when changing the tertiary filter stage (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:

  o Large screen monitor.

  o Automatic control of preset airflow volumes.

  o Sliding sash window with smart control.

  o Permanent monitoring of HEPA filters life span.

  o Alarms. Multilevel alarms, with redundancy functions.

  o Permanent display of working conditions.

  o Highest air flow stability both in case of transitional disturbances or to progressive filter clogging

  o Semi-automatic fumigation cycle (EN12297 tested and certified)

  o Continuous monitoring of front barrier air flow for the highest operator safety

  o Low barrier alarm

  o Power failure alarm

- Volt-free contact for remote monitoring of exhaust fan.

- Automatic reset of initial conditions in case of power failure

- Prepared for the installation of a 19inch LCD monitor on the back side (monitor not included)

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Numero REA MI – 2577880 Partita IVA e C. Fiscale: 11078210967 - Cap. Soc. Euro 1.000.000 i.v.
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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.

- Stainless Steel internal surfaces with 2B finishing (including spillage tray). Solid work surface (2 sections) and special designed front grill.

- Electrically operated sliding multilayer safety glass window (max opening at 120°)

- Comfortable 200mm front opening

- Easy to install retrofit options through lateral sides.

- Exposed exhaust Hepa filter for easy visual integrity check.

- Three stages of H14 class High Efficiency Particulate Air filters with 99.999% efficiency on .3micron particles (most penetrating particle diameter) (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 according to KTA 3601 Lüftungstechnische Anlagen in Kernkraftwerken)

- 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 when cabinet is switched on.

- High speed rinse and set up cycle performed, before reaching the SAFE operating mode.

- 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 exp 5

- Light intensity on work surface > 900 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)

- Max power (for each power point) 3Amps.

- Microprocessor equipped with analogical watch dog.

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

- Shipped in two parts (two pallets)

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STANDARD UTILITIES

Connectors for the utilities are located on the top of the cabinet towards the back.

Vacuum tap. On the right side.
Electrical socket. On the right side.
Mobile UV Kit socket. On the back wall, left side.

OPTIONAL ACCESSORIES

Description	Part No.
Backwall mounted UV light for Safemate Cyto 1.2	APK0114
Mobile UV Kit for S@femate Cyto 1.8	AKC0001

TECHNICAL SPECIFICATIONS

Model	S@FEMATE Cyto 1.2	S@FEMATE Cyto1.8
Part No.	LY74000	LY40000
External Size (lxdxh) mm	1380x780x2220	1990x840x2220
Working area size (lxdxh) mm	1230x600x700	1840x600x700
Front aperture – working position (mm)	195	195
Maximum front aperture (mm)	440	
Work surface	Solid work surface divided in sectors. Stainless steel AISI 304 with 2B finishing	
Weight (Kg)	340	450
HEPA filters efficiency	> 99,995% MPPS (according to EN1822.1)	
Exhausted air volume	≈440 m^3/h	≈650 m^3/h
Motorblower(s)	Centrifugal with speed autoregulation based on filter clogging status. IP55 protection level (2 blowers in 1.8 model)	
Power supply	230V ~ 50Hz	
Power (W)	400	750
Internal sockets	1 + 1 UV	2 + 1 UV
Fluorescent lamps	2x30W	2x58W
Lighting	1200 lux	
Sound pressure level	55 dB(A)	57 dB(A)

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