Pharmaceutical Division

PARTS AND GLASSWARE WASHERS

ML Series

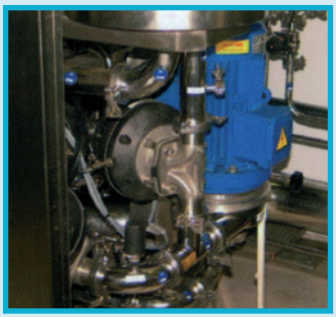
ICOS has a long experience in the treatment of parts and glassware normally used in the pharmaceutical industry.
This new range of ICOS machines show a series of innovative features that satisfy the strict requirements of the pharmaceutical industry (FDA, cGMP, GAMP 5, etc.).
These machines are identified by the item "ML".
The "ML" operating process consists of pre-washing, washing, rinsing, drying and cooling phases.

LOADING SIDE - TYPE ML 100 P-E

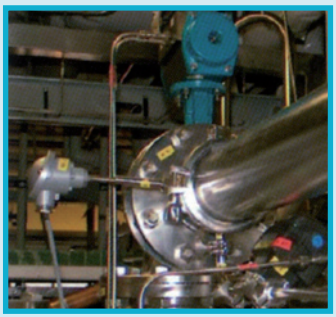
FIELD OF APPLICATION

These machines are designed for washing, disinfecting and drying of pharmaceutical products such as glassware, pipettes, machine parts, tanks, glass bottles, pill stamps, carboys, tubes, needles, etc.

Pharmaceutical Division



WATER RECYCLING LOOP WITH PRESSURE AND CONDUCTIVITY CONTROL



AIR HANDLING GROUP WITH TEMPERATURE CONTROL BY RTD

INTERNAL FINISHING OF WASHING CHAMBERS

MAIN FEATURES

- Distribution of load in racks/carts and baskets for a better performance results
- Washing and rinsing by means of simultaneous combination of water sprayed through nozzles by recycling pump and direct spray of pressurized WFI water; the suspended particles are skimmed off
- Disinfecting by means of dosing different type detergents
- Drying by HEPA filtered hot air at max. 130 °C
- Chamber and service area can be completely inspected/maintained through loading side (dirty area)
- Chamber doors of hinged type with double locking device
- Chamber doors made in accordance with requirements for clean environments
- Possibility of interfacing unloading door with isolator
- Machine equipped with connections for validation tests
- Various types of racks/carts and baskets for any kind of material
- Possibility of application of automatic loading & unloading of racks/trolleys

CONSTRUCTION FEATURES

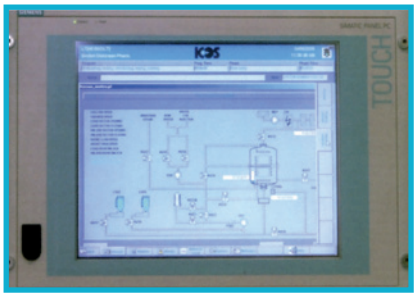
- The machine body and associated safety devices are manufactured and tested in compliance with the standards required by the country of destination. Unless there is a specific request, the machines and systems are manufactured and certified in compliance with the European CE mark
- Execution of machine in compliance with cGMP
- Use of sanitary FDA approved and 3A stamped components (valves, filters, piping, tri-clamp ferrules, pumps, etc.).
- Use of 316L stainless steel with roughness less than 0.5 µm (20 micro inches) on all components in contact with the process (machine body, machine doors, spray nozzles bars, process piping, instruments, valves, racks, internal carts, baskets, etc.)
- Respecting of 3-D dead Legs with the application of Zero-Static (0-Dead legs) components
- Respecting of 3 degree slope on process piping
- All internal corners of the chamber are radiuses as per cGMP requirement
- Orbital welding on all piping with tri-clamp ferrules ends
- No. 3 Water supplies of "pharma" type with last rinsing water sprayed directly to the spray nozzles/load
- Support frames, external fascia panels and any other "not-process" contact part made of AISI 304 stainless steel
- Machine body insulated with high density ceramic material and with external facing of stainless steel

CONTROL SYSTEM

The "ML" series are provided with a control system consisting of a controller (PLC), an operating panel (OP) or programmable computer (PC) and printer.
The control system manages the machine and its basic parameters, such as phases time, pump pressure, water pressure, water temperature, air temperature, detergents dosing, water conductivity, water PH, water level control it allows an easy interfacing with the operator and makes it possible to customize the process cycles and the manual operations.
In addition, the system produces a complete process documentation and assists the users in the operations of machine validation.

Note: A full description of the control system is contained in the brochure.

PLC: SIEMENS or ALLEN-BRADLEY



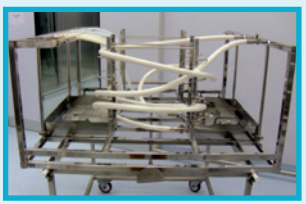
OP or PC: SIEMENS or ALLEN-BRADLEY
SCADA SYSTEM DESIGNED FOR FDA 21 CFR PART 11

STANDARDS AND NORMS

All ICOS machines are in compliance with the most updated standards in the quality of the materials used, in their accurate finishing, construction and process characteristics, such as:

- FDA Regulation 21 CFR part 210 and 211
- FDA Regulation 21 CFR part 11
- cGMP
- GAMP 5
- CE
- UL
- NEMA

RACKS/CARTS AND BASKETS OF DIFFERENT TYPES WITH POSSIBILITY OF CUSTOMIZED TYPE



PROCESS DATA

The process consists of combined phases and actions designed to provide maximum process flexibility.
The choice of times and phase succession makes it possible to obtain the most appropriate cycle for the charac teristics of the material to be processed.

PHASES	ACTIONS
loading of material	through prearranged rack/cart or basket
pre-washing	water loading, water heating, water recycling and water spraying through nozzles
cleaning	through different type of detergents
drain	water drain plus CIP action and PH measurement (optional)
washing	water loading, water heating, water recycling and water spraying through nozzles
disinfection	through different type of detergents
drain	water drain plus CIP action and PH measurement (optional)
1st rinse	water loading, water heating, water recycling and water spraying through nozzles
drain	water drain plus CIP action and PH measurement (optional)
2nd rinse	water loading, water heating, water recycling and water spraying through nozzles
conductivity control	on the water recycling loop
drain	water drain plus CIP action and PH measurement (optional)
drying	hot HEPA filtered air at max. 130°C
cooling	fresh HEPA filtered air at approx. 20°C
unloading of material	in clean environment by means of prearranged rack/cart or basket

Note: The above phases refer to a standard program.

ML SERIES - PARTS AND GLASSWARE WASHERS

Type	Capacity (litres / cu. ft.)	Chamber dimensions (mm / inches)			Overall dimensions (mm / inches)		
		Width	Height	Lenght	Width	Height	Lenght
ML 100	465 / 16.5	700 / 27.5	700 / 27.5	950 / 27.5	2150 / 84.5	2600 / 102	1164 / 45.5
ML 200	630 / 22	700 / 27.5	950 / 27.5	950 / 27.5	2150 / 84.5	2600 / 102	1164 / 45.5
ML 300	850 / 30	950 / 27.5	950 / 27.5	950 / 27.5	2400 / 95.5	2600 / 102	1164 / 45.5
ML 400	3800 / 134	1300 / 51	1950 / 76.5	1500 / 59	3000 / 118	3800 / 149.5	1790 / 70.5

ICOS RESERVES THE RIGHT TO MAKE PRODUCT CHANGES WITHOUT PRIOR NOTIFICATION

CSQ UNI EN ISO 9001

IQNet CERTIFIED QUALITY SYSTEM

rev. 01/12

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