

FURTHER INFORMATION



OUR SECTORS:

- **ELECTRICAL**

ELECTRICAL INDUSTRY: HOW TO MANAGE MEDIUM AND HIGH VOLTAGE

- **AUTOMOTIVE**

EXPERIENCE SINCE 1970 IN THE DESIGN AND CONSTRUCTION OF VACUUM SYSTEMS FOR THE AUTOMOTIVE SECTOR

- **MEDICAL INDUSTRY**

PERFECT INSULATORS FOR EARLY DIAGNOSIS AND PATIENT PROTECTION

- **PHARMACEUTICAL**

BRIZIO BASI PRODUCES FREEZE DRYERS AND PUMPING UNITS; WE ALSO PROVIDES CERTIFICATIONS AND MAINTENANCE OF SYSTEMS

- **COMPOSITES**

THE INNOVATIVE MATERIAL OF THE FUTURE

- **AVIONIC**

BRIZIO BASI HAS BEEN PRODUCING SYSTEMS TO SERVE THE RADAR PRODUCTION, TEST AND BURN-IN SYSTEMS FOR OVER 20 YEARS

- **GLASS**

GLASS AND PROCESSING TOOLS INDUSTRY

- **CULTURAL HERITAGE**

EXPERIENCE SINCE 1970 IN THE DESIGN AND CONSTRUCTION OF VACUUM SYSTEMS FOR THE CULTURAL HERITAGE SECTOR



BRIZIO BASI

HIGH VACUUM TECHNOLOGY

LOCAL REPRESENTATIVE



Ing. Brizio Basi & C. S.A.S.
Via Bernardo Rucellai 23, 20126 Milano (MI)
Tel: 022552751
Fax: 022570291
E-mail: info@briziobasi.it
Web: www.briziobasi.it
C.F. / P.Iva: 00775310154
Codice SDI: M5UXCR1



BACKGROUND

BRIZIO BASI IS RECOGNISED AS A WORLD LEADER IN FREEZE DRYING TECHNOLOGY WITH A REPUTATION FOR QUALITY WORLDWIDE.

FOR OVER 47 YEARS BRIZIO BASI HAS BEEN MANUFACTURING FREEZE DRYING AND ASSOCIATED EQUIPMENT FOR INDUSTRY AND RESEARCH.

IN THE SPECIALISED FIELD OF PHARMACEUTICALS AND BIOLOGICAL PRODUCTS BRIZIO BASI ENJOYS AN INTERNATIONAL

REPUTATION FOR QUALITY, CHOICE, FLEXIBILITY AND TECHNOLOGY.

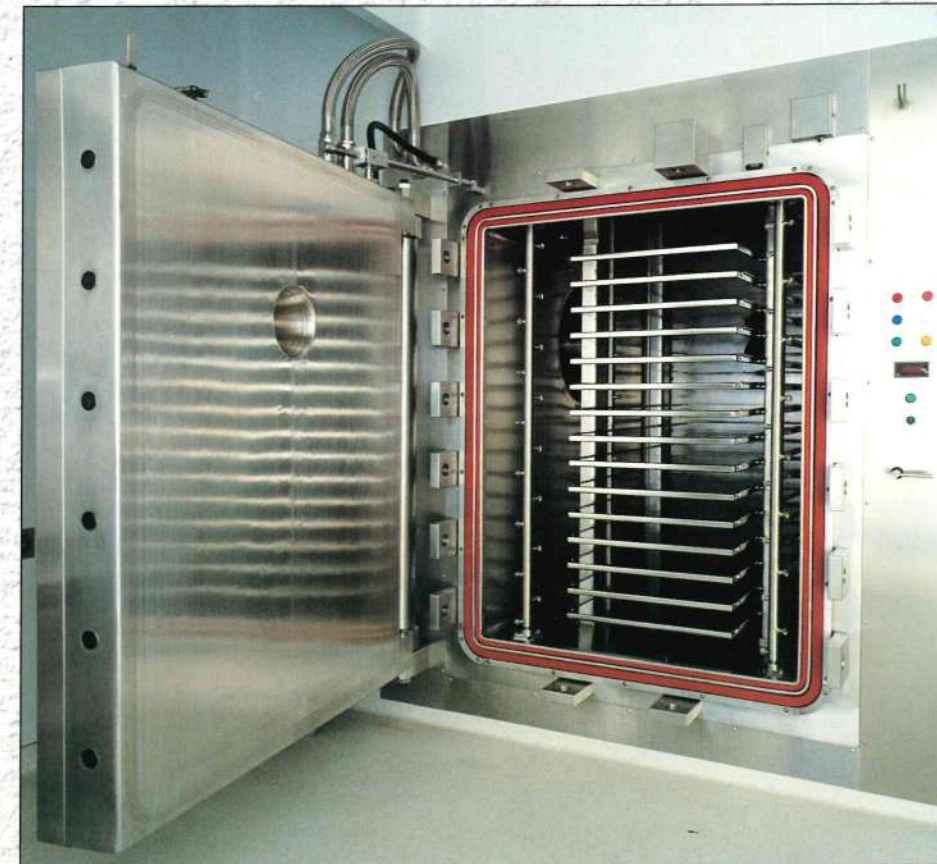
AS AN AIR LIQUIDE GROUP COMPANY, BRIZIO BASI EXPORTS A SIGNIFICANT PART OF ITS PRODUCTION FROM ITS MODERN FACTORY SITUATED 10KM NORTH WEST OF MILAN



WHAT WE OFFER

- A wide range of machines that can be customised to meet your exact requirements.
- Unsurpassed experience in design for sterile applications to meet cGMP and all regulatory guidelines.
- The ability to manufacture large and complex systems together with all accessories - freezing tunnel, central refrigeration group, automatic loading and unloading, storage chambers, fully automated processes.
- Pilot and research machines manufactured to the same high quality as the industrial units with all accessories to permit scale-up.
- Validated and proven control systems from a specialist group with direct knowledge of the lyophilisation process.
- The highest possible quality of manufacture for reliable and long lasting machines backed by an in house internationally recognised quality control programme (ISO 9000).
- A large team of experienced technicians to help with maintenance and give support for problem solving.
- In the World of Freeze Drying Brizio Basi has unrivalled experience with 47 years of steady growth and an established name the world over for excellence. A vendor with all these features to give you confidence for the next 20 years.
- Quality · Choice · Technology · Flexibility · Experience.

Technical Features CHAMBERS



● Quality

All Brizio Basi chambers are built to exacting standards - our manufacturing pressure vessel codes are among the toughest in the world - to give long trouble-free service life. Brizio Basi also builds to the American and all European codes.

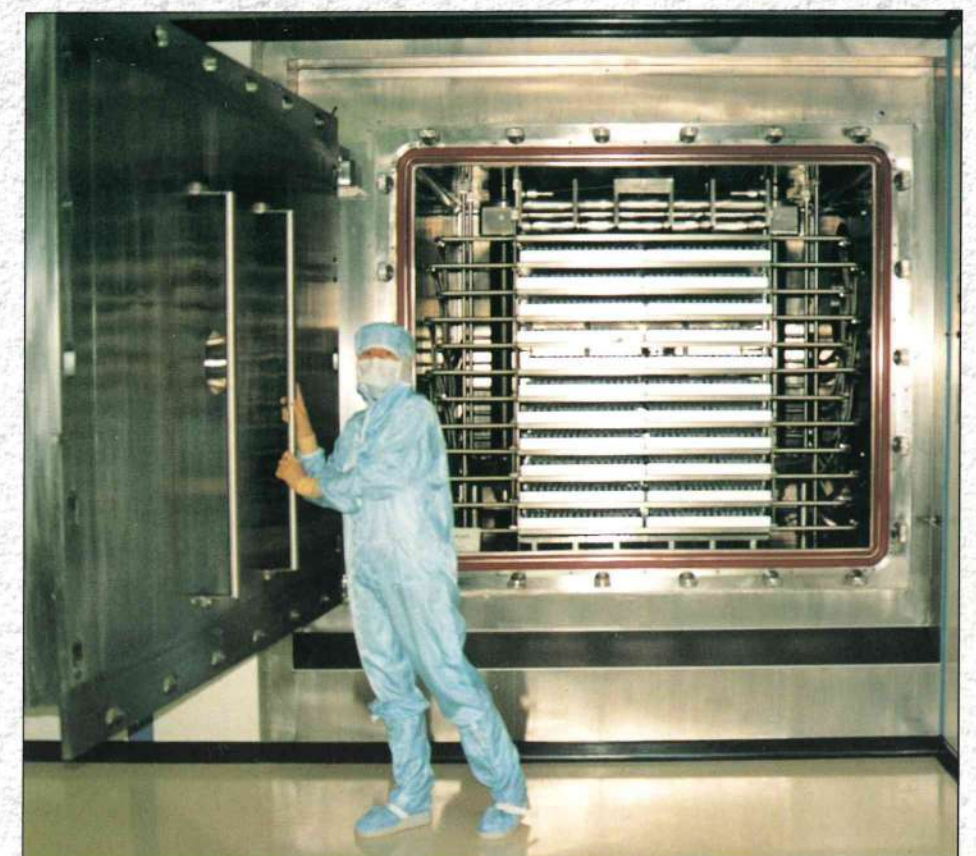
● Attention to detail

Design is careful in all details to avoid crevices, to ensure cleaning is practicable and sterility, where called for, is assured.

Connections are designed to avoid dead-legs. Insulation is sealed for high performance and long life, stainless steel panels provide the perfect external finish.

● Finish

Only the best low carbon stainless steels are used. All welds are ground flush and final polishing, depending on the application, will be a minimum of 220 grit (Ra 1.0µm) with mirror finish (Ra<0.5µm) or electropolishing as options.



Technical Features DOORS

● Safety is paramount

Built to the same high standards as the chambers, fully interlocked with operator protection against excess temperature and pressure.

● Operator friendly

Low friction hinge design for easy opening of even the largest doors.

● Simplicity

Dual gasket sealing eliminates complex or friction locking systems.

● Sophistication

Brizio Basi has just the right choice in central locking devices - bayonet, single lever, peripheral locking for ease of operation. Sliding type, either horizontal or vertical as needed. Brizio Basi recognises that in steam sterilisable machines, multiple handwheel designs are not safe today.

● Flexibility

Double ended or pass-through option with interlocks enabling operations



to be optimised with loading and unloading using optional pizza door.

● Sterility

Flush mounted closure panels to seal clean room opening.

ABOVE: NEW DOOR HINGE SYSTEM.

BELOW: PERIPHERAL LOCKING DOOR ON 25M² UNIT.



STOPPERING

Brizio Basi offers a unique combination of either hydraulic or screw type stoppering. Variable shelf spacing is an option with all Brizio Basi stoppering systems.

● Hydraulic type

This is of the bridge design which ensures no non-sterile component enters the chamber before stoppers are inserted. The possibility of hydraulic fluid leaking into the drying chamber is completely eliminated with this design.

Stoppering operation is bottom up.

● Screw type

Revolutionary patented design operates using two helical screws driving upper reinforced plate from which all shelves are suspended.

No component enters or leaves the chamber during operation.

No excessive height needed in machine area for mechanism.

All components are sterilised with the chamber and non particle shedding.

Constant level or low level loading is possible. Precise operation ensures exact heights without creep, especially important with auto loading systems.

Moving shelves is a very smooth operation, enabling tall unstable vials or ampoules to be carried without risk of falling. **No other stoppering system can offer all these advantages.**

SHELVES

● Quality

Heavy gauge construction means confidence for life even with routine stoppering. Flatness assured to $\pm 0.5\text{mm/m}$ to give perfect contact with trays or vials. Temperature distribution $\pm 1^\circ\text{C}$ to give proper homogeneity to all product treatment, even in the largest machines.

● Flexibility

Easy repositioning system ensures shelf area can be used to maximum advantage where many types of vial are handled. Shelf spacings are calculated to give the best capacity at minimum cost.



Technical Features SHELVES AND STOPPERING

STANDARD RANGE OF FREEZE DRIERS

Model number	SMH	100	150	200	350	501	601	801	1201	1215	1515	1715	2010	2015	2020	4015	5015
Minimum shelf area	m ²	0.5	1.0	1.0	2.0	3.5	3.9	6.9	7.9	10.9	12.5	15.6	17.6	20.6	29.4	24.7	28.0
Maximum shelf area	m ²	1.5	3.0	3.0	4.0	6.0	7.9	12.8	13.7	20.2	23.4	26.5	29.4	35.3	43.1	40.5	47.6
Shelf size width	mm	500	500	500	500	500	630	630	630	1000	1000	1000	1260	1260	1260	1500	1560
Shelf size length	mm	1000	1000	1000	1000	1000	1560	1560	1560	1560	1560	1560	1560	1560	1560	1500	1800
Minimum no. of shelves		1	2	2	4	7	4	7	8	7	8	10	9	11	15	11	10
Maximum no. of shelves		3	6	6	8	12	8	13	14	13	15	17	15	18	18	18	17
Nominal ice capacity	kg	20	40	40	60	100	100	200	200	200	300	300	400	400	500	500	600

STANDARD RANGE OF FREEZE DRIERS

Services required

- 3 phase electrical power
- Water for compressor cooling
- Hot water or steam for de-icing
- Compressed air for valve actuation
- Air/N² for vacuum release
- Water for CIP

Characteristics

- Shelf temperature: +80°C/-55°C
- Condenser temperature: -75°C
- Nominal vacuum limit: 5 x 10⁻³mbar
- Pumping time to 10⁻¹mbar ≤20 mins
- Silicon oil 5 cst used as circulating thermal transfer medium
- Electrical resistance heating 1.5kW/m² shelf
- Main compressors used for shelf or condenser cooling
auxiliary compressor only for shelf cooling
- Refrigerants R403B/R402A/R404A/R507
- Leak rate ≤ 1 x 10⁻²mbar litre/second

Options (for client to specify)

- Internal/external process condenser
- Type of door: handwheel/central locking/pivot type/
peripheral locking/bayonet/sliding
- 316L stainless steel or better
- Polishing: mirror/electropolish
- Additional compressors
- Standby vacuum pumps/chemical resistant pump/
oil filtration/dry pump/Roots blower/pump protection filter
- Dual circulation pumps
- Sterilization by steam 123°C or higher (SIP)
- In-line sterilising filter 0.2μ for air with valving for
integrity test
- Stoppering (screw type or hydraulic)
- Loading/unloading system
- In place cleaning (CIP)
- Liquid nitrogen cooling
- SYRIUS control and regulation
- SYRIUS Windows version
- SYREN - duplicate computer package
- SYRAUTO - SYRIUS with plc (Allen Bradley, Modicon,
Siemens...)

STERILISATION AND CIP (CLEANING IN PLACE)

Many of Brizio Basi lyophilisers are delivered for high technology applications requiring sterilisation.

Designs are continually improving to eliminate cold spots and dead legs in pipework backed up by intensive validation studies.

All Brizio Basi chambers can be also sterilised chemically where regulations permit. However, in common with current international practice, steam is still the preferred medium.

Included in the standard package is an air/nitrogen inlet filter with valve manifold permitting in-situ integrity test.

Brizio Basi has always used a liquid-ring vacuum pump for air removal and drying the chamber, now adopted as the industry standard.

Brizio Basi chambers are designed to drain fully, and the drain is easily accessed from the door.

Brizio Basi offers several approaches to CIP using steam alone, spray balls or rotating nozzles.



HEAT TRANSFER SYSTEM

● Setting industry standards

Brizio Basi was first to use silicon oil and the most efficient and maintenance-free brazed plate heat exchangers now adopted by others.

● Simplicity

The entire system is designed to avoid the need for filters, driers, relief valves and other devices which only create maintenance problems.

● Flexibility

Open drive or canned type circulating pumps; duplicate pumps offer additional security, always valved for maintenance.

● Technology

Non CFC refrigerant or liquid nitrogen cooling available. Brizio Basi was first to deliver a large industrial lyophiliser to use only LN2 technology.

All Brizio Basi systems are ready to accept new refrigerants when commercially available. Central refrigeration systems are optional for large installations to reduce costs.

Brizio Basi guarantees -55°C to $+80^{\circ}\text{C}$ using HFC refrigerants and electric heating.

LIQUID NITROGEN

Together with Air Liquide, Brizio Basi offers a real alternative to

conventional refrigerants with proven low temperature technology.

Liquid nitrogen can be used either as a low temperature option - for example in trapping organic solvents or as the main cooling medium for both shelves and condenser.

The advantages of liquid nitrogen are as follows:

- Eliminates costly compressor maintenance.
- Eliminates need for electricity and cooling water for compressors.
- Cooling capacity is constant over the temperature range.
- Saving on space in installation.
- Eliminates noise problems.

Brizio Basi offers real low temperature technology all over the world backed by the world's largest manufacturer of liquefied gases.

REFRIGERATION

● Setting industry standards

Brizio Basi is a pioneer in the very best technology to provide efficient and long lasting results.

For example:

- Designed for ease of maintenance.
- Vibration eliminators at every point.
- Readable gauges.
- Refrigerant level indication.
- Discharge temperature control.
- CFC free for today's environment.

HEAT TRANSFER SYSTEM LIQUID NITROGEN REFRIGERATION



PROCESS CONDENSERS AND LOADING SYSTEMS



PROCESS CONDENSERS

● Flexibility

Brizio Basi is unique in offering maximum flexibility in the placement of the condenser - internal or external which means behind, at the side, above or below the lyo chamber. No other manufacturer can offer a top mounted condenser with stoppering.

Ice capacity from 10kg to 700kg.

● Efficiency

High efficiency vertical coil design with truly independent multiple circuits and dedicated compressors. Demonstrably good at minimising oil backstreaming.

Plate type designs available for special applications.

● Technology

No dead areas as in horizontal designs. The coiled coil minimises oil entrainment in the condenser, reducing problems with compressors.

Brizio Basi uses only the best separating valves, either butterfly type with long lasting seal retained in place by vacuum assistance or flap type used in top mounted condensers.

LOADING SYSTEMS

Brizio Basi specialises in giving custom designed solutions for each application whether for bulk product, vials or ampoules:

- Loading at constant level.
- Loading shelf by shelf or all shelves at one time.
- Pass through or single door solutions.
- Intermediate storage before and after lyophilisation.
- Loading with or without trays.
- Protective environments during loading and unloading.
- High speed systems handling up to 30,000 vials per hour are already proven by Brizio Basi
- Ampoule handling is a speciality.

TOP LEFT: TOP MOUNTED CONDENSER AND LOADING SYSTEM.

LEFT: BATCH UNLOADING

INSTALLATION

● Flexibility

Brizio Basi offers unrivalled attention to detail to eliminate costly maintenance problems. Only Brizio Basi matches the lyophiliser to your available space. Multi-level installations also possible.

● Assurance

All components numbered and coded to ensure your installation provides ease of maintenance.

● Back-up

Brizio Basi selects internationally available components to reduce costly inventory and ensure compatibility.

QUALITY CONTROL

Where possible all installations are fully tested prior to shipping.

Machines are built in the factory to follow exactly the final lay-out.

Full design, installation and operational qualification support.

Complete documentation is provided to meet the user's needs and those of regulatory authorities.

Only the very best standard of workmanship is good enough for Brizio Basi. Attention to detail is critical, as is presentation of all mechanical and electrical components.

Brizio Basi sets the standards for others to follow.

SUPPORT

Brizio Basi offers training programmes for practical freeze drying and maintenance.

Large team of technicians fully trained to assist with problems or regular maintenance. Service is available locally all over the world.

Qualified technical staff for technology support in many countries.

Brizio Basi offers advice and experience in most freeze drying applications, participating with its clients in determining a mutually satisfactory result.

AFTER SALES SERVICE

