

# Kuhner shaker



## SB2500-Z

Orbital shaken bioreactor for production

Scale-up without compromising quality

### SB2500-Z

#### **Production scale bioreactor**

with 500 to 2500 L working volume

The next generation of the orbital shaken bioreactor (OSB) SB2500-Z is now available for the cultivation of human, mammalian, plant, and insect cells in a single-use bag. The user-friendly system has comparatively short set-up times and can be easily deployed in production. The SB2500-Z is designed to comply with GMP requirements and regulations.

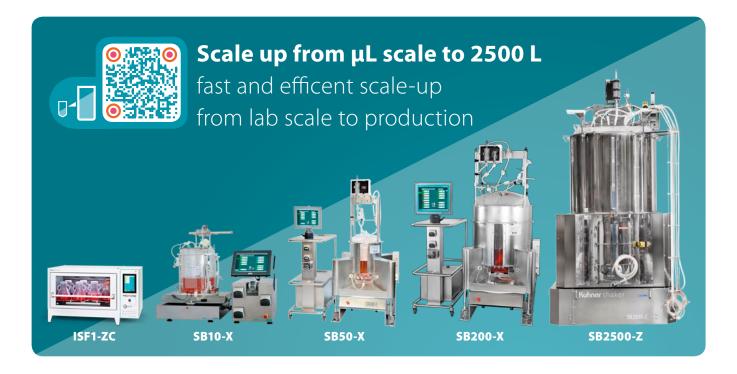


# Fast and trouble-free scale-up from lab scale to production scale

- Circular vessel geometry and power input over the vessel wall create equal, consistent hydrodynamics in all scales of shaken bioreactors: MTPs (μL to mL), shake flasks (mL to L), and Kuhner's orbital shaken bioreactors (1.5 to 2500 L).
- Reproducible cultivation conditions throughout the scaling process due to equal hydrodynamics.
- Simplicity of technology: speed of scale-up and process development is fast with a lower cost of implementation compared to stirred systems.
- Smaller orbital shaken bioreactors can provide inoculum for larger bioreactors, e.g., a culture from the SB50-X or SB200-X can serve as a preculture for the SB2500-Z.

### Single-use bags for short set-up times

- Gamma-irradiated single-use bags and pre-calibrated, non-invasive sensors: eliminate need for elaborate calibration, cleaning, and sterilizing procedures.
- No invasive stirrer or mixing device required: zero wearing of moving parts, no sterility problems of the slide ring sealing.
- Shorter set up times compared with stainless steel stirred tank reactors of the same size.
- Very flexible regarding different cultivation processes: large range of working volumes; no risk of cross contaminations.
- Standard single-use bag can be customized to meet exactly the customer's requirements.





Gentle cultivation environment with low shear stress: evenly distributed power input due to orbital motion, bubble-free surface aeration, and almost no frothing.

GMP Good Manufacturing Practice (GMP): designed to comply with GMP requirements and regulations.

Orbital shaking motion provides large gas transfer area: this guarantees an adequate oxygen supply of the cultivated cells and efficient CO<sub>2</sub> stripping.

Kuhner products: documentation, development, and production along with the full product life cycle are constantly enhanced to match the requirements of 21 CFR and GAMP 5.



#### Mammalian/human cells

(e.g., Chinese Hamster Ovary (CHO, CHO-K1, CHO-DG44, ExpiCHO), HEK 293 cells, duck cells (AGE1.CR), Hybridoma)

#### Stem cells

(e.g., hMSC)

#### **Insect cells**

(e.g., Spodoptera frugiperda (Sf-9, Sf-21), H-5)

#### **Plant cells**

(e.g., Nicotiana tabacum L.CV BY2, Vitis Vinifera, Theobroma cacao, Algae)

#### **Shaking applications**

(e.g., mixing of mRNA)

#### **Food applications**

- Processed beef meat
- Processed poultry meat (duck, chicken)
- Plant cells (chocolate production)





#### **Cooling**

For the cooling option, a cooling ring is embedded in the base plate of the SB2500-Z. Cooling is achieved by connecting an external cooling device. An integrated valve, controlled by the software, regulates the set point temperature. Temperature ramps are easily programmed and processed.



### Liquid flow measurement

The clamp-on sensors of Levitronix® are designed for a high-precision, non-invasive flow measurement of fluids in flexible tubing.



#### **IQ/OQ - Documentation**

The IQ/OQ-Documentation (Installation Qualification and Operation Qualification) required for GMP procedures is available as an option and can be provided at the customer's premises. Our Kuhner GMP & Compliance team is happy to answer any questions regarding the GMP compliance of the SB2500-Z bioreactor.



#### **Lockable USB port**

For customers with e.g., GMP processes, a lockable USB port can be incorporated in the control unit.





### **Kuhner shaker**A family-owned business

Kuhner shaker, founded in 1949 in Basel, Switzerland, is a science first shaker manufacturer renowned worldwide for our uncompromising shakers, incubator shakers, and orbital shaken bioreactors. From bench top shakers to large scale industrial shaking machines, we offer machines of the highest quality. We commit to earning trusting client relationships which will span decades.



## Comprehensive consulting, lab trainings and seminars

We provide application-oriented support, seminars, and lab trainings. Training courses are conducted at our training lab in Switzerland, onsite at the customer's premises, or online. Our training lab features for instance orbital shaken bioreactors for cultivations up to 200 L, providing the ideal training environment for cell culture and scale-up cultivations. The Shaking Technology Forum by Kuhner is a helpful resource for users of shaken cultivation vessels, providing support, information, and a publication database. www.shakingtechnology.com



## **Custom-made** solutions by the Kuhner Atelier

Does our existing range of products not meet your requirements? Simply contact us – custom made solutions are the daily business of our specialists from the Kuhner Atelier department. We generate the optimal solution for your shaking machine or orbital shaken bioreactor system.



#### **Services**

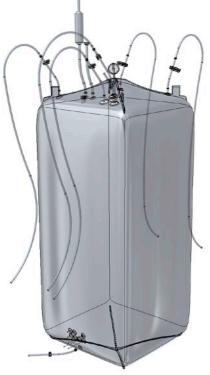
We provide support and advice for each customer right from the start. Our services are performed by our trained service team personally at your premises. We support our customers in implementation, maintenance, and repair of all Kuhner products. This includes upgrades of functionalities and updates of software for all Kuhner shakers and OSBs. We offer one-time services or service contracts extending over several years, depending on our customer's needs. We also perform calibrations specific to our customer's requirements.



Single-use bag in detail

#### Single-use bag

- · Gamma-irradiated 3D single-use bags
- Working volume of 500-2500 L
- · No mixing device or stirrer required
- · No cleaning or sterilizing procedures
- Short set-up times
- · Light and easy to handle
- Integrated, non-invasive optical-chemical pH (2x) and DO (2x) sensors
- Ports incorporated for inoculation, feeding and supplementing, sampling, and harvesting
- Two exhaust gas lines (one as back-up)
- One standard single-use bag available with customization option



3D bag design of the SB2500-Z single-use bag

#### Bag-in-bag design

To ensure maximum protection for the cell culture in the 2500 L scale, the single-use bag consists of two interlocking welded, separate chambers with a total of seven plastic layers.



#### **Components and material**

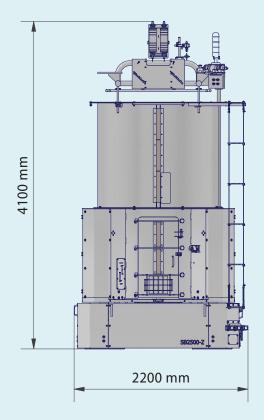
Our single-use bags are made from multi-layered USP class VI plastic material. The product contact material is polyethylene (LDPE), which is routinely used for biological processes. The gas barrier is made of ethylene vinyl alcohol (EVOH), which provides extremely low gas permeability. The outer layer is made of polyethylene (PE).

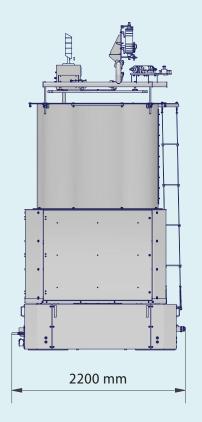
#### **Entegris**

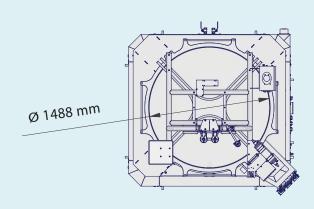
Entegris is our partner for the development and production of our 2500 L single-use bag. Entegris is able to provide a complete portfolio of single-use bioprocessing solutions for development, scale-up, and bulk production, helping to solve our customers' most complex biomanufacturing challenges.

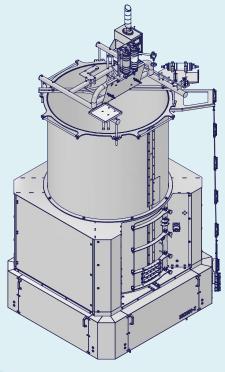


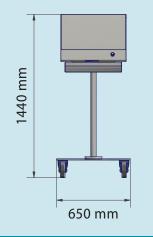
### Dimensions













Please contact us to receive an information folder with the local requirements for setting up the SB2500-Z.

General		
Working volume range	500 - 2500 L	
Dimensions (width x depth x height)	approx. 220 x 220 x 410 cm	
Required footprint bioreactor	5 m <sup>2</sup>	
Required footprint operation site	12 m <sup>2</sup>	
Weight (empty)	3200 kg	
Power consumption steady state	approx. 1000 Wh	
Power consumption max.	approx. 11500 Wh	
Mains connection	400 V / 50 Hz	
Connection for power supply	Adjusted to power outlet of recipient country	
Interface	Ethernet (1x RJ45)	
Language of manual and safety instructions	Adjusted to official language of recipient country	
Ambient conditions	10 - 35 °C / max. 85% r.h.	
Material casing	Stainless steel V2A / 1.4301	
IP protection class	IP43	
Ambient noise level	approx. 60 dB	
Bag nominal value	approx. 3700 L	
Bag contact layer	LDPE	
User interface		
Touchscreen size	21.5 inches / 54.6 cm	
Touchscreen type	10-finger multi-touch, glove-friendly, capacitive	
Resolution	1920 x 1080 Pixel (Full-HD)	
Material casing	stainless steel & safety glass	
IP protection class	IP67	
Control software	SB2500-Z SCADA	
Operation menu language	English	
	2.19.13.1	
Shaking control	2.19.15.1	
	Helical-bevel gearmotor	
Shaking control		
Shaking control Drive concept	Helical-bevel gearmotor	
Shaking control Drive concept Shaking frequency range	Helical-bevel gearmotor 0-60 rpm	
Shaking control  Drive concept  Shaking frequency range  Setting, digital	Helical-bevel gearmotor 0-60 rpm 1 rpm	
Shaking control Drive concept Shaking frequency range Setting, digital Shaking diameter (fix)	Helical-bevel gearmotor 0-60 rpm 1 rpm 100 mm (orbital motion)	
Shaking control Drive concept Shaking frequency range Setting, digital Shaking diameter (fix) Accuracy, absolute	Helical-bevel gearmotor 0-60 rpm 1 rpm 100 mm (orbital motion) ±1 rpm	
Shaking control Drive concept Shaking frequency range Setting, digital Shaking diameter (fix) Accuracy, absolute Acceleration	Helical-bevel gearmotor 0-60 rpm 1 rpm 100 mm (orbital motion) ±1 rpm adjustable	
Shaking control Drive concept Shaking frequency range Setting, digital Shaking diameter (fix) Accuracy, absolute Acceleration Active brake	Helical-bevel gearmotor  0-60 rpm  1 rpm  100 mm (orbital motion)  ±1 rpm  adjustable  adjustable inductive sensor for additional speed measure-	
Shaking control Drive concept Shaking frequency range Setting, digital Shaking diameter (fix) Accuracy, absolute Acceleration Active brake Shaking frequency sensor	Helical-bevel gearmotor  0-60 rpm  1 rpm  100 mm (orbital motion)  ±1 rpm  adjustable  adjustable inductive sensor for additional speed measure-	
Shaking control  Drive concept  Shaking frequency range  Setting, digital  Shaking diameter (fix)  Accuracy, absolute  Acceleration  Active brake  Shaking frequency sensor  Temperature control	Helical-bevel gearmotor 0-60 rpm 1 rpm 100 mm (orbital motion) ±1 rpm adjustable adjustable inductive sensor for additional speed measurement and detection of drivetrain defect	
Shaking control Drive concept Shaking frequency range Setting, digital Shaking diameter (fix) Accuracy, absolute Acceleration Active brake Shaking frequency sensor Temperature control Cooling	Helical-bevel gearmotor 0-60 rpm 1 rpm 100 mm (orbital motion) ±1 rpm adjustable adjustable inductive sensor for additional speed measurement and detection of drivetrain defect optional	
Shaking control Drive concept Shaking frequency range Setting, digital Shaking diameter (fix) Accuracy, absolute Acceleration Active brake Shaking frequency sensor  Temperature control Cooling Temperature max. (with 2500 L)	Helical-bevel gearmotor 0-60 rpm 1 rpm 100 mm (orbital motion) ±1 rpm adjustable adjustable inductive sensor for additional speed measurement and detection of drivetrain defect  optional 40 °C	
Shaking control Drive concept Shaking frequency range Setting, digital Shaking diameter (fix) Accuracy, absolute Acceleration Active brake Shaking frequency sensor  Temperature control Cooling Temperature max. (with 2500 L) Temperature min. (with 2500 L)	Helical-bevel gearmotor  0-60 rpm  1 rpm  100 mm (orbital motion)  ±1 rpm  adjustable  adjustable inductive sensor for additional speed measurement and detection of drivetrain defect  optional  40 °C  slightly above RT (with optional cooling)	
Shaking control  Drive concept  Shaking frequency range  Setting, digital  Shaking diameter (fix)  Accuracy, absolute  Acceleration  Active brake  Shaking frequency sensor  Temperature control  Cooling  Temperature max. (with 2500 L)  Temperature min. (with 2500 L)  Setting, digital	Helical-bevel gearmotor 0-60 rpm 1 rpm 100 mm (orbital motion) ±1 rpm adjustable adjustable inductive sensor for additional speed measurement and detection of drivetrain defect  optional 40 °C slightly above RT (with optional cooling) 0.1 °C	
Shaking control  Drive concept  Shaking frequency range  Setting, digital  Shaking diameter (fix)  Accuracy, absolute  Acceleration  Active brake  Shaking frequency sensor  Temperature control  Cooling  Temperature max. (with 2500 L)  Temperature min. (with 2500 L)  Setting, digital  Temperature control accuracy	Helical-bevel gearmotor 0-60 rpm 1 rpm 100 mm (orbital motion) ±1 rpm adjustable adjustable inductive sensor for additional speed measurement and detection of drivetrain defect  optional 40 °C slightly above RT (with optional cooling) 0.1 °C ± 0.3 °C	
Shaking control Drive concept Shaking frequency range Setting, digital Shaking diameter (fix) Accuracy, absolute Acceleration Active brake Shaking frequency sensor  Temperature control Cooling Temperature max. (with 2500 L) Temperature min. (with 2500 L) Setting, digital Temperature control accuracy Heating rate (with 2500 L)	Helical-bevel gearmotor 0-60 rpm 1 rpm 100 mm (orbital motion) ±1 rpm adjustable adjustable inductive sensor for additional speed measurement and detection of drivetrain defect  optional 40 °C slightly above RT (with optional cooling) 0.1 °C ± 0.3 °C 2 °C / h	
Shaking control Drive concept Shaking frequency range Setting, digital Shaking diameter (fix) Accuracy, absolute Acceleration Active brake Shaking frequency sensor  Temperature control Cooling Temperature max. (with 2500 L) Temperature min. (with 2500 L) Setting, digital Temperature control accuracy Heating rate (with 2500 L) Cooling rate (with 2500 L)	Helical-bevel gearmotor 0-60 rpm 1 rpm 100 mm (orbital motion) ±1 rpm adjustable adjustable inductive sensor for additional speed measurement and detection of drivetrain defect  optional 40 °C slightly above RT (with optional cooling) 0.1 °C ± 0.3 °C 2 °C / h 1 °C / h (with active coolant supply at 16 °C)	
Shaking control  Drive concept  Shaking frequency range  Setting, digital  Shaking diameter (fix)  Accuracy, absolute  Acceleration  Active brake  Shaking frequency sensor  Temperature control  Cooling  Temperature max. (with 2500 L)  Temperature min. (with 2500 L)  Setting, digital  Temperature control accuracy  Heating rate (with 2500 L)  Cooling rate (with 2500 L)	Helical-bevel gearmotor  0-60 rpm  1 rpm  100 mm (orbital motion)  ±1 rpm  adjustable  adjustable  inductive sensor for additional speed measurement and detection of drivetrain defect  optional  40 °C  slightly above RT (with optional cooling)  0.1 °C  ± 0.3 °C  2 °C / h  1 °C / h (with active coolant supply at 16 °C)  9000 W	
Shaking control  Drive concept  Shaking frequency range  Setting, digital  Shaking diameter (fix)  Accuracy, absolute  Acceleration  Active brake  Shaking frequency sensor  Temperature control  Cooling  Temperature max. (with 2500 L)  Temperature min. (with 2500 L)  Setting, digital  Temperature control accuracy  Heating rate (with 2500 L)  Cooling rate (with 2500 L)  Power of heating  Heating concept	Helical-bevel gearmotor  0-60 rpm  1 rpm  100 mm (orbital motion)  ±1 rpm  adjustable  adjustable  inductive sensor for additional speed measurement and detection of drivetrain defect  optional  40 °C  slightly above RT (with optional cooling)  0.1 °C  ±0.3 °C  2 °C / h  1 °C / h (with active coolant supply at 16 °C)  9000 W  resistance (attached to vessel wall)  7500 W (depending on available coolant	

pH and DO control		
pH measurement	2x optical sensors (integrated in bag)	
Measurement range	pH 5.0 - 9.0	
Measurement accuracy	pH $\pm$ 0.05 at pH 7 with one point calibration pH $\pm$ 0.10 at pH 7 with pre-calibration	
Control range	pH 5.5 - 8.5	
Control accuracy	$pH \pm 0.1$	
Drift per day	pH < 0.005	
Setting, digital	pH 0.1	
Temperature range	up to 50 °C	
Control strategy	variable CO <sub>2</sub> conc. in gas mixture and/or acid/base pumps	
DO measurement	2x optical sensors (integrated in bag)	
Measurement range	0% – 130 % DO	
Measurement accuracy	+/- $0.4\%$ O <sub>2</sub> at $20.9\%$ O <sub>2</sub> in the gas mixture +/- $0.05\%$ O <sub>2</sub> at $0.2\%$ O <sub>2</sub> in the gas mixture.	
Control range	0% – 100% DO	
Control accuracy	±1% DO	
Drift per day	< 0.015 % DO	
Setting, digital	1 % DO	
Temperature range	up to 50 °C	
Control strategy	variable O <sub>2</sub> conc. in gas mixture	
Gas mixing (FlowCon)		
Number of mass flow controllers	5 (1 per gas and 1 for total gas flow)	
Mass flow controller concept	thermal	
Input	up to 4 gases (air, O <sub>2</sub> , N <sub>2</sub> and CO <sub>2</sub> )	
Input pressure range	2.0 - 2.5 bar	
Output flow rate control range air for bag infilling	1.0 - 200 L/min	
Output flow rate control range air for process control	1.0 - 70 L/min	
Output flow rate control range O <sub>2</sub> for process control	0.8 - 60 L/min	
for process control	0.8 - 60 L/min	
for process control  Output flow rate control range N <sub>2</sub> for process control  Output flow rate control range CO <sub>2</sub>	0.8 - 60 L/min	
for process control  Output flow rate control range N <sub>2</sub> for process control  Output flow rate control range CO <sub>2</sub> for process control	0.8 - 60 L/min 0.1 - 15 L/min	
for process control  Output flow rate control range N <sub>2</sub> for process control  Output flow rate control range CO <sub>2</sub> for process control  Flow rate accuracy of full scale	0.8 - 60 L/min 0.1 - 15 L/min ± 0.8 %	
for process control  Output flow rate control range N <sub>2</sub> for process control  Output flow rate control range CO <sub>2</sub> for process control  Flow rate accuracy of full scale  Setting, digital	0.8 - 60 L/min 0.1 - 15 L/min ± 0.8% 0.1 L/min	
for process control  Output flow rate control range N <sub>2</sub> for process control  Output flow rate control range CO <sub>2</sub> for process control  Flow rate accuracy of full scale  Setting, digital  Pressure safety measurement	0.8 - 60 L/min 0.1 - 15 L/min ± 0.8% 0.1 L/min	
for process control  Output flow rate control range N <sub>2</sub> for process control  Output flow rate control range CO <sub>2</sub> for process control  Flow rate accuracy of full scale  Setting, digital  Pressure safety measurement  Filter heater control	0.8 - 60 L/min  0.1 - 15 L/min  ± 0.8 %  0.1 L/min in gas output flow and bag headspace	
for process control  Output flow rate control range N <sub>2</sub> for process control  Output flow rate control range CO <sub>2</sub> for process control  Flow rate accuracy of full scale  Setting, digital  Pressure safety measurement  Filter heater control  Exhaust filter capacity  Temperature maximum (at RT with	0.8 - 60 L/min  0.1 - 15 L/min  ± 0.8%  0.1 L/min in gas output flow and bag headspace  2 (2 separate filter heaters)	
for process control  Output flow rate control range N <sub>2</sub> for process control  Output flow rate control range CO <sub>2</sub> for process control  Flow rate accuracy of full scale  Setting, digital  Pressure safety measurement  Filter heater control  Exhaust filter capacity  Temperature maximum (at RT with 60 L/min flow rate)	0.8 - 60 L/min  0.1 - 15 L/min  ± 0.8%  0.1 L/min in gas output flow and bag headspace  2 (2 separate filter heaters)  60°C	
for process control  Output flow rate control range N <sub>2</sub> for process control  Output flow rate control range CO <sub>2</sub> for process control  Flow rate accuracy of full scale  Setting, digital  Pressure safety measurement  Filter heater control  Exhaust filter capacity  Temperature maximum (at RT with 60 L/min flow rate)  Heating concept	0.8 - 60 L/min  0.1 - 15 L/min  ± 0.8 %  0.1 L/min in gas output flow and bag headspace  2 (2 separate filter heaters)  60 °C  resistance	
for process control  Output flow rate control range N <sub>2</sub> for process control  Output flow rate control range CO <sub>2</sub> for process control  Flow rate accuracy of full scale  Setting, digital  Pressure safety measurement  Filter heater control  Exhaust filter capacity  Temperature maximum (at RT with 60 L/min flow rate)  Heating concept  Power of heating per filter heater	0.8 - 60 L/min  0.1 - 15 L/min  ± 0.8 %  0.1 L/min in gas output flow and bag headspace  2 (2 separate filter heaters)  60 °C  resistance  55 W	
for process control  Output flow rate control range N <sub>2</sub> for process control  Output flow rate control range CO <sub>2</sub> for process control  Flow rate accuracy of full scale  Setting, digital  Pressure safety measurement  Filter heater control  Exhaust filter capacity  Temperature maximum (at RT with 60 L/min flow rate)  Heating concept  Power of heating per filter heater  Setting, digital	0.8 - 60 L/min  0.1 - 15 L/min  ± 0.8 %  0.1 L/min in gas output flow and bag headspace  2 (2 separate filter heaters)  60 °C  resistance  55 W  0.1 °C	
for process control  Output flow rate control range N <sub>2</sub> for process control  Output flow rate control range CO <sub>2</sub> for process control  Flow rate accuracy of full scale  Setting, digital  Pressure safety measurement  Filter heater control  Exhaust filter capacity  Temperature maximum (at RT with 60 L/min flow rate)  Heating concept  Power of heating per filter heater  Setting, digital  Control accuracy	0.8 - 60 L/min  0.1 - 15 L/min  ± 0.8 %  0.1 L/min in gas output flow and bag headspace  2 (2 separate filter heaters)  60 °C  resistance  55 W  0.1 °C  ± 2 °C	

Technical data subject to change.

Pumps			
Peristaltic pumps (up to 3 mobile pumps)	2 small pumps for acid, base, or feed	1 large pump for inoculation and harvest	
Туре	Watson-Marlow 630PnN/R	Watson-Marlow 730PnN/R	
Flow rates	0.010 L/min to 2.400 L/min	1.000 L/min to 33.330 L/min	
Tube wall thickness	3.2 mm	4.8 mm	
Flow measurement	By internal measurement of pumps and addi	By internal measurement of pumps and additional up to 3 flow meters (Leviflow®)	

### **Kuhner** shaker

#### **Shakers & Accessories**

Represented by:



Adolf Kühner AG • since 1949

Dinkelbergstrasse 1 CH – 4127 Birsfelden (Basel) Switzerland phone +41 (0) 61 319 93 93 office@kuhner.com

