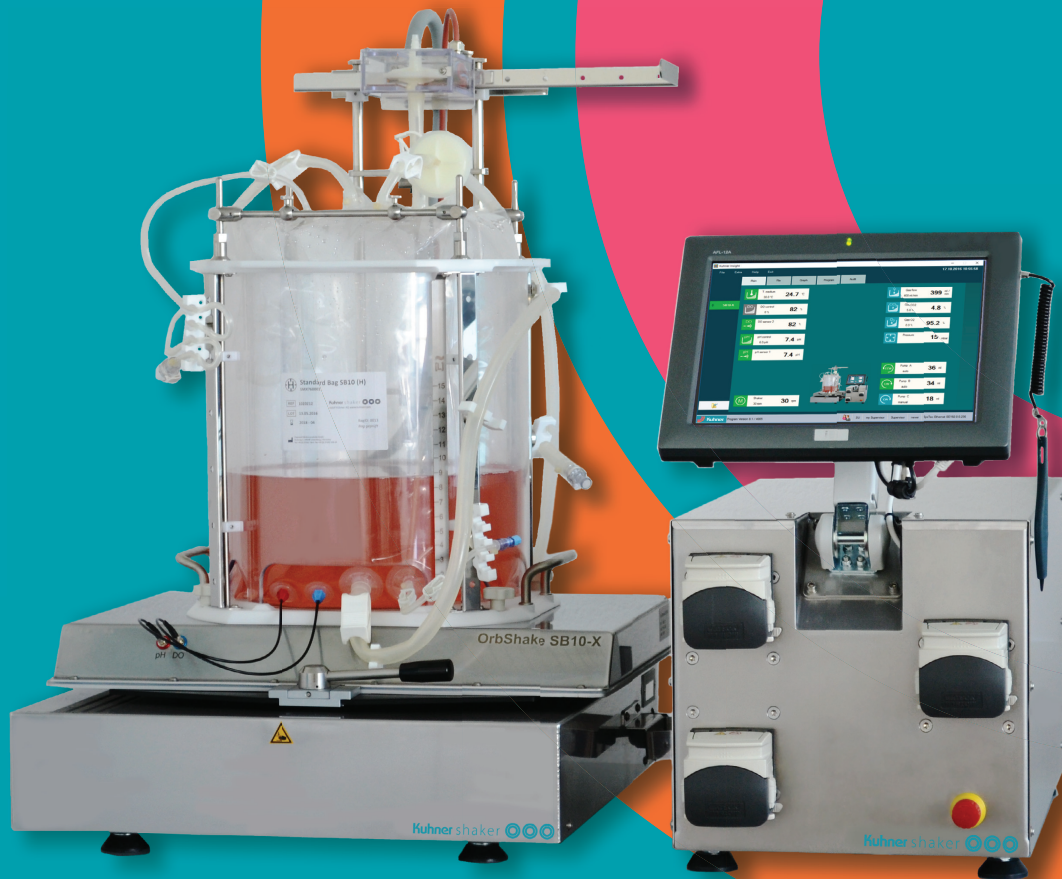


Kuhner shaker

SB10-X (OSB)

Orbital shaken benchtop bioreactor
for single-use bags





The SB10-X is an orbital shaken benchtop bioreactor system for the cultivation of human, mammalian and plant cells in a single-use bag. It consists of six modules (excluding the bag) and has a working volume from 4 litres up to 12 litres. The SB10-X can be used in research, process development or as a pilot scale bioreactor.

Performance characteristics

- + Cultivation of human, mammalian and plant cells
- + Fast, simple set up
- + Easy scale-up
- + Online measurement and control of pH and DO
- + Three different single-use bags available

Single-use bag for a fast and simple set up

The cylindrical vessel accepts a single-use 3D bag. This bag requires no additional mixing device, enables quick set up times and eliminates elaborate cleaning and sterilising procedures. Various ports are incorporated to allow feeding, inoculation, harvesting and sampling. The standard bag has built-in optical sensors for pH/DO allowing online measurement and control of pH and DO in the medium. Two other bag types are available: a basic single-use bag with no optical sensors and a perfusion bag for ATF and TFF perfusion.

Orbital motion

The orbital motion of the SB10-X ensures efficient liquid mixing. It facilitates high oxygen transfer rates with low shear forces. Mechanical stress on the cells is reduced thanks to bubble-free surface gassing with almost no frothing. This motion is particularly suitable for microcarrier cultivation. The SB10-X uses the unique Kuhner direct drive which is very robust and provides accurate control of the orbital speed.

2 Vessel module

3 Filter heater



Trouble free scale-up

The SB10-X fills a gap in the scale-up chain from commonly used single-use flasks all the way up to 50 L and 200 L bioreactors. The consistent hydrodynamics of shaken bioreactors provide reproducible cultivation conditions throughout the volume range. The culture from the SB10-X can serve as a preculture for the SB50-X and SB200-X. The SB10-X can also be used as a pilot scale bioreactor.

Heating and online pH & DO measurement 1

The tray module, which is fixed onto the ES-X shaker module, contains integrated heating and the connections for online pH and DO measurement.

Vessel module 2

Special emphasis has been placed on developing a user-friendly vessel module. The vessel together with its bag can be easily detached by the user and carried to the clean bench.

Filter heater 3

A filter heater for one exhaust filter is placed above the vessel module. The magnetic mounting makes handling the filter heater very simple and allows its location in various places. The filter heater combats water vapour condensation in the outlet air preventing blockages in the membrane.

Control unit and software

The compact and functional design of the control unit provides easy handling and monitoring of the bioprocess parameters. The control unit has an integrated and adjustable 12" touch screen with USB and Ethernet connections. The Kuhner Insight application software for data recording, calibration, programming and controlling is user-friendly and 21 CFR Part 11 compliant. Control of pH/DO, medium temperature, shaking frequency and gas flow rate and mixture is possible.

Pumping system

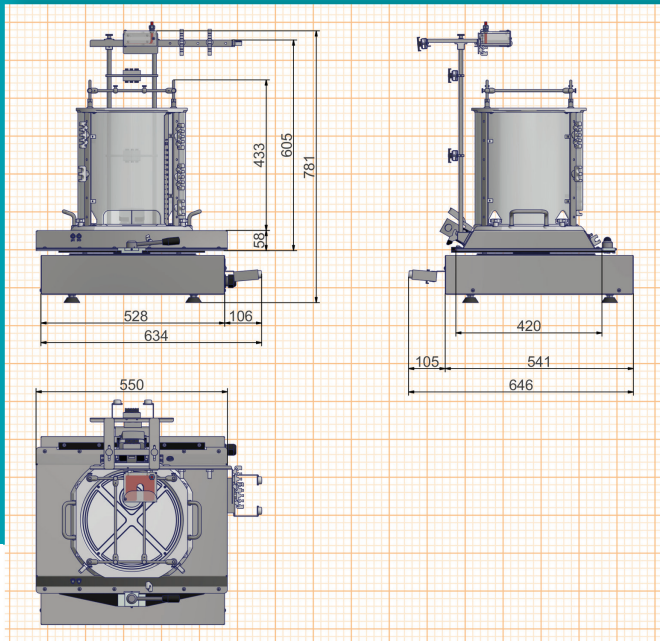
The control unit incorporates three peristaltic pumps which allow aseptic fluid management. This enables simple regulation of the pH-value, feeding and the transfer of the culture media (scale-up or processing).

Gas mixing

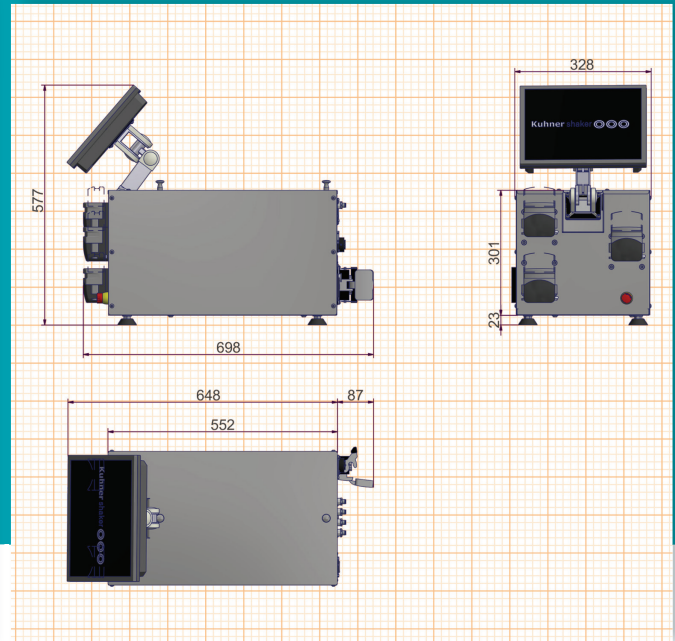
The SB10-X control unit has an integrated gas mixing device (FlowCon).

Whether stabilizing the pH with CO₂, or preventing low dissolved oxygen concentrations, the gas mixer meets all user needs. Four mass flow controllers (N₂, O₂, CO₂ and air or gas mixture) ensure highly accurate and reproducible gas mixing. An integrated pressure sensor prevents over pressure in the bioreactor. Step limits can be freely programmed by the user. Integrated air filters and back pressure valves ensure interference free and long operating times for the FlowCon.

Dimensions (mm) SB10-X Shaken bioreactor



Dimensions (mm) Control unit



Technical data

• SB10-X Order number: SMX7600

includes 6 modules:

- Shaker module ES-X

Bioreactor:

- Tray module
- Vessel module
- Cable and tube management module
- Filter heater
- Control unit

• Shaken bioreactor

Working volume	4 L - 12 L
Total bag volume	approx. 24 L
Weight (bioreactor incl. shaker)	approx. 75 kg without liquid
Required footprint (excl. control unit)	669 mm x 646 mm

• Shaker module ES-X

Motor	modified ES-X benchtop shaker
Shaking diameter	50 mm (orbital motion) shaking diameter is adjustable (12.5 mm, 25 mm, 50 mm)
Shaking speed	20 rpm - 140 rpm (when used with SB10-X)
Loading, maximum	25 kg
Setting, digital	1 rpm
Accuracy, absolute	± 0.5 rpm
Active brake	adjustable
Ambient temperature	5°C - 40°C
Casing	stainless steel 1.4301

• Mains connection

SMX1021	220 - 240 V / 50-60 Hz
SMX1023	110 - 120 V / 50-60 Hz
SMX1024	95 - 105 V / 50-60 Hz

• Temperature control

Heating	resistance heater (100 W), integrated in tray module
Temperature max.	40 °C
Temperature min.	approx. ambient temperature (no cooling)
Temperature accuracy	± 0.25 °C
Temperature distribution	8 mm thick aluminium plate provides homogenous temperature distribution of resistance heater

• pH and DO control Integrated in tray module

pH measurement	principle: optical chemosensor
Range	pH 5.5 - pH 8.5
Accuracy (chemosensor)	± pH 0.05 at pH 7 with one point calibration ± pH 0.10 at pH 7 with pre-calibration
Drift	< pH 0.005 per day
Temperature range	up to 50 °C
DO measurement	principle: optical chemosensor
Range	0 % - 100 % DO
Accuracy (chemosensor)	± 0.1 % O ₂ at 20.9 % O ₂
Accuracy (system)	± 10 % DO
Drift	< 0.015 % O ₂ per day
Temperature range	up to 50 °C

• Filter heater

Capacity	1 exhaust filter
Casing	polycarbonate
Heating	resistance heater (6 W)
Max. temperature	approx. 40 °C at 23 °C ambient temperature
Control	orange LED light indicates that filter heater is active and working



- Control unit (SMX76011)**
 - Weight: approx. 30 kg
 - Required footprint: 698 mm x 328 mm
 - Casing: Stainless steel 1.4301
 - Interface: 2 x CAN-Bus
Optional: EMI-60, NET-60
- Touch screen**
 - Display: 12.1" screen (resistive)
front is splash proof and dust protected (IP 64)
 - Resolution: 1024 x 768
 - Cooling: passive with no fan
 - Main memory: 2 GB (1.6 GB usable)
 - Interfaces: 4 x USB, 2 x RS 232, 2 x LAN, 1 x VGA
- Software**
 - Kuhner Insight application software 4**
 - Monitoring: pH & DO, shaking speed, temperature, gas flow and mixture, pressure
 - Calibration: pre-calibrated sensors in bag
 - Recalibration: one point recalibration is possible
 - Applicable: Win 7 & 10
 - GMP: 21 CFR Part 11 compliant

- Pumps**
 - 3 peristaltic pumps**
 - Type: Watson-Marlow 313 VBM/D
 - Rollers: 3
 - Power: 70 W
 - Maximum speed: 100 rpm
 - Tube: 1.6 mm wall thickness
 - Delivery Pressure: max. 2 bar

Technical data subject to change

Tube ID [mm]	Flow rates [mL/min] at 100 rpm
0.5	3.4
0.8	7
1.6	27
3.2	100
4.8	220
6.4	360
8	500

3 Gas mixing:
Mixing up to four gases
Gas mixtures can also be connected



• **Gas mixing device (FlowCon) 5**

Number of mass flow controllers	4
Ambient conditions	5 °C – 40 °C, max. 85 %rH
Input	up to 4 gases (air, oxygen, nitrogen, carbon dioxide) different gas mixtures can also be connected push in connector for tubes OD 6 mm required input pressure: 1 bar – 2 bar
Output	1 (tube fitting optimal for tubing 9 x 1 mm) Flow rates: N ₂ : 0.1 L min ⁻¹ – 1.99 L min ⁻¹ O ₂ : 0.1 L min ⁻¹ – 1.99 L min ⁻¹ CO ₂ : 0.1 L min ⁻¹ – 1.4 L min ⁻¹ air: 0.1 L min ⁻¹ – 1.99 L min ⁻¹ accuracy: ± 1.3 % of full scale
Pressure measurement	gas output: pressure sensor DELOS SI (Jumo), integrated in FlowCon
Differential pressure	0 mbar – 100 mbar (programmable) the pressure limits can be adjusted
Gas filter	integrated, prevents blocking of mass flow controllers

Technical data subject to change

Options

IQ-OQ Documentation

IQ-OQ (Installation Qualification and Operation Qualification) is an equipment qualification required for GMP procedures. Documentation is available from Kuhner and Qualification services can also be provided at the customer's premises.

Interfaces

Two additional interfaces, EMI-60 and NET-60, are available as options.

EMI-60:

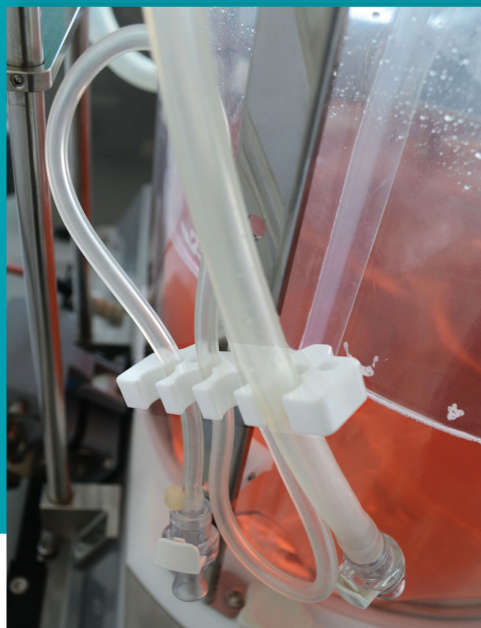
The EMI-60 has several interfaces: two analogue outputs and two individually configurable alarm relays.

NET-60:

NET-60 allows the machine to be connected to almost all conventional Bus-systems and to OPC servers.

5 Light protection jacket

7 MagFix



Accessories

Single-use bag

Kuhner offers three different single-use bag types to meet all user needs. Each pack contains three bags.

These gamma-irradiated bags for the Kuhner shaken bioreactor require no additional mixing device, enable quick set up times and eliminate elaborate cleaning and sterilising procedures. All bags have a working volume from 4 litres up to 12 litres. Various ports are incorporated to allow feeding, inoculation, harvesting and sampling.

The standard bag (SMX760001) has built in optical sensors for pH and DO which allow non-invasive online measurement and control of pH and DO. This standard bag is suitable for ATF perfusion.

The basic single-use bag (SMX760002) is the same as the standard bag, but has no optical sensors.

The perfusion bag (SMX760003) has two exhaust filters and is equipped with additional tubes and ports for TFF perfusion. ATF perfusion is also possible.

Order number

SMX760001	3 x standard single-use bags for SB10-X with optical chemosensors for pH/DO and tubes
SMX760002	3 x basic single-use bags for SB10-X with no optical sensors
SMX760003	3 x perfusion single-use bags for SB10-X with 2 exhaust filters, optical chemosensors for pH/DO and additional tubes

Overpressure valve & glass fibers (spare parts)

SMX76007	Red overpressure valve, OD 9mm
SMX876001	2 glass fibers for pH/DO probes, length 40cm

Light protection jacket 6

Order number: SMX76005

This light protection jacket is easily placed over the vessel module. It protects light sensitive media or products from UV and artificial light as well as daylight.

MagFix 7

Order number: SMX76006

MagFix is a set of 8 magnetic tube holders to help secure and guide all the tubing. It consists of 6 units for tubing OD 6mm/11mm and 2 units for tubing OD 15mm. The tubing fits easily into the slots on each unit. These magnetised holders can be attached to various steel surfaces on the vessel module, cable management module and shaker module of the SB10-X. The magnets on these units are so strong that they are also effective through the light protection jacket.



Shakers & Accessories

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