SB10-X (OrbShake)
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.
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 OrbShakers. The SB10-X can also be used as a pilot scale bioreactor.

Heating and online pH & DO measurement
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
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
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.
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: ± 0.1 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 % O₂ at 20.9 % O₂
- Accuracy (system): ± 10 % DO
- Drift: < 0.015 % O₂ 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 with touch screen and pumps

**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**
  - 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

<table>
<thead>
<tr>
<th>Tube ID [mm]</th>
<th>Flow rates [mL/min] at 100 rpm</th>
</tr>
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<tbody>
<tr>
<td>0.5</td>
<td>3.4</td>
</tr>
<tr>
<td>0.8</td>
<td>7</td>
</tr>
<tr>
<td>1.6</td>
<td>27</td>
</tr>
<tr>
<td>3.2</td>
<td>100</td>
</tr>
<tr>
<td>4.8</td>
<td>220</td>
</tr>
<tr>
<td>6.4</td>
<td>360</td>
</tr>
<tr>
<td>8</td>
<td>500</td>
</tr>
</tbody>
</table>

Technical data subject to change
**Gas mixing:**
Mixing up to four gases
Gas mixtures can also be connected

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**Gas mixing device (FlowCon)**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
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<tbody>
<tr>
<td>Number of mass flow controllers</td>
<td>4</td>
</tr>
<tr>
<td>Ambient conditions</td>
<td>5 °C – 40 °C, max. 85 %rH</td>
</tr>
<tr>
<td>Input</td>
<td>up to 4 gases (air, oxygen, nitrogen, carbon dioxide)</td>
</tr>
<tr>
<td></td>
<td>different gas mixtures can also be connected</td>
</tr>
<tr>
<td></td>
<td>push in connector for tubes OD 6 mm</td>
</tr>
<tr>
<td></td>
<td>required input pressure: 1 bar – 2 bar</td>
</tr>
<tr>
<td>Output</td>
<td>1 (tube fitting optimal for tubing 9 x 1 mm)</td>
</tr>
</tbody>
</table>
|                                              | Flow rates:  
| N₂                                           | 0.1 L min⁻¹ – 1.99 L min⁻¹  
| O₂                                           | 0.1 L min⁻¹ – 1.99 L min⁻¹  
| CO₂                                          | 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 |

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**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.
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.

<table>
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<tr>
<th>Order number</th>
<th>Description</th>
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<tbody>
<tr>
<td>SMX760001</td>
<td>3 x <strong>standard</strong> single-use bags for SB10-X with optical chemosensors for pH/DO and tubes</td>
</tr>
<tr>
<td>SMX760002</td>
<td>3 x <strong>basic</strong> single-use bags for SB10-X with no optical sensors</td>
</tr>
<tr>
<td>SMX760003</td>
<td>3 x <strong>perfusion</strong> single-use bags for SB10-X with 2 exhaust filters, optical chemosensors for pH/DO and additional tubes</td>
</tr>
</tbody>
</table>

**Overpressure valve & glass fibers (spare parts)**

<table>
<thead>
<tr>
<th>Order number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMX76007</td>
<td>Red overpressure valve, OD 9mm</td>
</tr>
<tr>
<td>SMX876001</td>
<td>2 glass fibers for pH/DO probes, length 40cm</td>
</tr>
</tbody>
</table>

**Light protection jacket**

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**

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.