

Xcellerex XDR-50 MO fermentor system

MICROBIAL CULTURE

The single-use Xcellerex™ XDR-50 MO stirred-tank fermentor system is a purpose-built 50 L stirred-tank system for growth of microbial cultures (Fig 1). The system design is based on extensive user input and in-house use. The single-use system is a cost-effective, easy-to-operate industrial tool featuring no inherent cross-contamination risk, minimized water consumption, and fast batch-to-batch turnover. The system is designed with a two-stage impeller combination that provides good mixing, exceptional power input, and high oxygen transfer required for microbial fermentation.

The fermentor system comprises a jacketed, stainless steel vessel, essential process instrumentation, robust automation, and an optimized, single-use bioreactor bag assembly. The system, combined with a self-contained temperature control unit (TCU), only requires gas supply and electrical power to be fully operational.

XDR-50 MO fermentor offers the following benefits:

- Cell growth comparable to conventional stainless steel microbial fermentors
- No rotating shafts or seals, eliminating leakage risks
- Efficient agitation from a powerful bottom magnetic drive, for a well-mixed tank
- Two-stage impeller supporting high oxygen transfer rates
- Dimple-jacketed heat transfer surface for efficient cooling and heating

System overview

The single-use XDR-50 MO fermentor is a 50 L turnkey, modular system that delivers performance comparable with hard-piped, stainless steel fermentor systems. The system's turnkey design enables fast system installation and start-up. The single-use technology eliminates time-consuming and costly cleaning and cleaning validation operations and allows for



Fig 1. XDR-50 MO fermentor vessel, I/O cabinet, and portable X-Station control console.

rapid batch-to-batch changeover along with increased process flexibility compared with fixed, stainless steel, hardpiped vessels.

The XDR-50 MO fermentor system comprises three key elements: a fermentor vessel with baffles and condenser; a versatile I/O cabinet; and a plug-and-play portable X-Station control console. The fermentor vessel features a jacketed heat-transfer surface, including the bottom head, for efficient cooling and heating; a high-performance bottom mounted, magnetically coupled drive; load cells for weight measurement; an exhaust filter heater; and removable baffles. An optional second exhaust filter heater may be added, providing a ready-to-use back-up exhaust filter. The I/O cabinet houses all critical process instrumentation including mass flow controllers (MFCs), peristaltic pumps, and probe transmitters. An external TCU is available as an option, to provide fluid for heating and cooling to the vessel jacket. The stand-alone X-Station control console features an intuitive user interface, data historian, and industrial-quality automation hardware and software, enabling real-time data acquisition, accurate process control, and convenient, real-time trending.

The heart of the XDR-50 MO fermentor system is the XDA single-use bag assembly, designed to meet the stringent requirements of microbial fermentation. The single-use bag assembly is based on the design and materials used in the proven XDR technology for mammalian cell culture. A shaftless and seal-less agitator provides powerful agitation of the culture with minimal risk of leakage. All fermentor bags incorporate a pressure sensor to maintain bag integrity during demanding fermentation runs.

System components

Efficient vessel with baffles and condenser

The XDR-50 MO fermentor vessel includes a large probe window in the front lower sidewall. The probe window is large enough to accommodate a dual-element resistance temperature detector (RTD) sensor, a dual-outlet sampling port, and redundant pH and DO probes. Probes and their cables are supported by a support bar located in front of the probe window. An additional vessel port in the lower sidewall is available for use with custom bag designs. A rupture disc protects the jacket from overpressure and the connected relief pipe directs jacket contents to just above the floor. The 304 grade stainless steel (304 SS) vessel uses a dimpled heat-transfer surface to provide efficient cooling and heating of the culture. Three integrated load cells enable accurate measurement of culture weight. The aspect ratio of the fermentor vessel is 1.5:1.

The system is equipped with three removable baffles, a Peltier (thermoelectric) exhaust condenser (Fig 2), and a heated exit air filter. The use of baffles enhances agitation and improves mixing, with mass transfer rates in excess of 1000 mM/h possible. The exhaust condenser removes moisture that may be entrained in the exhaust gas due to high sparge gas flow rates.

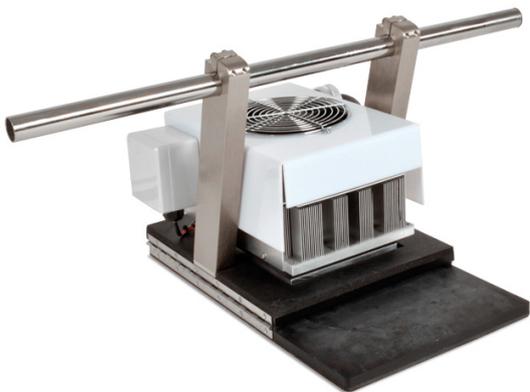


Fig 2. Peltier exhaust condenser.

Versatile I/O cabinet

Fabricated in 304 SS, the NEMA4X-rated I/O cabinet houses devices for liquid and gas management as well as field devices such as pH and DO transmitters, power supplies, circuit breakers, and fuses. Profibus™ is the standard bus protocol used in device communication and communication to X-Station. Ethernet is available for network connection and connection to other automation platforms (e.g., DeltaV™, Honeywell, and Siemens, among others).

Liquid management

The I/O cabinet can be configured with up to four internal and two external variable-speed peristaltic pumps with ranges that support liquid addition or removal for the 50 L vessel. The peristaltic pumps can be configured for use with various control loops, including base addition for pH, substrate feeds, and level control.

Gas management

The XDR fermentor employs two mass flow controllers, one for air and one for oxygen. Each mass flow controller has a maximum flow rate of one vessel volume per minute (VVM). This configuration allows for a variety of gas control scenarios, including a classic three-stage fermentation cascade: stage 1 = RPM, stage 2 = air flow, and stage 3 = oxygen flow.

Measurement of pH and DO

The integration of pH or DO probe with the fermentor bag is determined by the bag port. Conventional, reusable pH and DO probes are used. The probes provide real-time data, monitored throughout the entire process using Wonderware™ software. The XDR-50 MO fermentor uses well-known and industry-proven probe technology: the pH probe relies on liquid chemistry and the DO probe is polarographic with a stainless steel construction. Transmitters are used for integration into the I/O panel.

Measurement of dissolved carbon dioxide (CO₂)

CO₂ is often an important fermentation parameter to monitor. CO₂ measurement in the XDR-50 MO fermentor is available in two options. The first option incorporates a panel-mounted CO₂ transmitter within the I/O cabinet. The second option uses a standalone bench-top CO₂ transmitter. The second option can be useful when the need for CO₂ measurement arises after the system has been installed. Conventional, reusable, insertion-type, probe technology is used for monitoring of dissolved CO₂.

Plug-and-play X-Station mobile control console

X-Station is a standalone, portable control console featuring intuitive user interface, data historian, and industrial-quality automation hardware and software. The control system provides real-time data acquisition, enables accurate process control, and offers convenient, real-time trending. X-Station is capable of measuring and controlling up to six XDR-50 MO fermentor systems independently and simultaneously.

Inside the 304 SS cover is housed a scalable programmable logic controller (PLC) and a server-class computer running the

user interface and data historian software. X-Station comes with a 19" touchscreen, industrial, wash down-resistant mouse, a QWERTY keyboard, and built-in uninterruptible power supply (UPS). Profibus and Ethernet communication standards are included for equipment and local area network connectivity.

Single-use bag assembly

The single-use bag assembly consists of a USP Class VI low-density polyethylene fluid contact layer, tubing for liquid addition and harvest, impeller/sparger assembly, sampling and probe ports, pressure sensor, and filtered gas lines. The exhaust path is fitted with an exhaust condenser to prevent exhaust filter fouling, making use of the integrated exhaust condenser bag. The sparger has eight 1/4" open pipe ports providing the high gassing rates required to maintain the dissolved oxygen (DO) levels necessary for microbial cultures. Robust agitation is provided by a powerful magnetic drive and a two-stage impeller (Fig 3). The first stage is a Rushton impeller, which delivers excellent power into the system. The second stage is an axial-flow impeller operating in a pump down mode, improving gas residence time. The two-stage impeller combination results in very high oxygen transfer (> 1000 mM/h) to the culture medium.

Additional consumables available optionally include sample manifolds (5- and 10-position) and foam traps.



Fig 3. Two-stage impeller for efficient, application-specific performance.

Applications

The XDR-50 MO modular design allows for transition between microbial and cell culture processes, with the changing of bags and accessories for a dual-purpose system that is well-suited for development work. XDR-50 MO fermentor has successfully been used to cultivate a wide range of organisms including *E. coli*, *Pseudomonas*, and yeast. In cell culture mode, the system has been used for cultivation of CHO cells, Vero cells, and MDCK cells.

System specifications

System specifications are listed in Table 1.

Table 1. XDR-50 MO system specifications

Specification	
Max working volume (L)	50
Min working volume (L)	25
Volume turn-down ratio	2:1
Vessel i.d. (in)	12
Aspect ratio (H/D)	1.5:1
Baffles	3
Vessel	Jacketed 304 SS
Filter heater assembly	1
Additional filter heater assemblies (optional)	1
Impeller	Two-stage: six-bladed Rushton-type with a pitch-blade, axial flow impeller on top
Standard bag assembly	29-0410-60
Custom bag assembly	Available on request
Condenser (optional)	29-0880-39
Process instrumentation	
pH probes	1 or 2
DO probes	1 or 2
MFC* (standard)	2 [†]
Pumps built-in	3 pumps are standard, 1 additional pump optional [‡]
Pumps external	2 available optionally
Temperature control unit	3 kw heater/1 hp chiller combination
Load cells	3
X-Station control unit	
Integrated control panel	Built to GAMP5 standards/ 21 CFR Part 11 compliant _s
Hardware	Allen Bradley™ (Rockwell Automation Inc.)
Operator interface	Wonderware HMI [¶] (Invensys Systems)
Data historian	Wonderware

* Mass flow controllers

[†] Dual-purpose systems come with six MFCs, two for fermentation and four for cell culture.

[‡] Dual-purpose systems use all four pumps.

[§] Customer will need to implement appropriate operating procedures to be fully 21 CFR part 11 compliant. The XDR is built to support this two-part compliance.

[¶] Human-machine interface

Note: For specifications of the XDR cell culture bioreactor systems, please see data files 29-0929-25 and 29-0929-27.

Ordering information

Related literature	Code number
Xcellerex XDR-10 cell culture bioreactor system, Data file	29-0929-27
Xcellerex XDR cell culture bioreactor systems, Data file	29-0929-25
Xcellerex XDUO Quad Mixing System, Data file	29-0483-66
Xcellerex XDM Quad Mixing System, Data file	29-0483-67

For more information on the XDR-50 MO fermentor system, please contact your local sales representative.

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