cytiva

Xuri Cell Expansion System W25

Product Documentation



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1 Introduction

Purpose of this document

This document provides an overview of Xuri™ Cell Expansion System W25, general system specifications, a description of the material conformity of the system, and the EC Declaration of conformity.

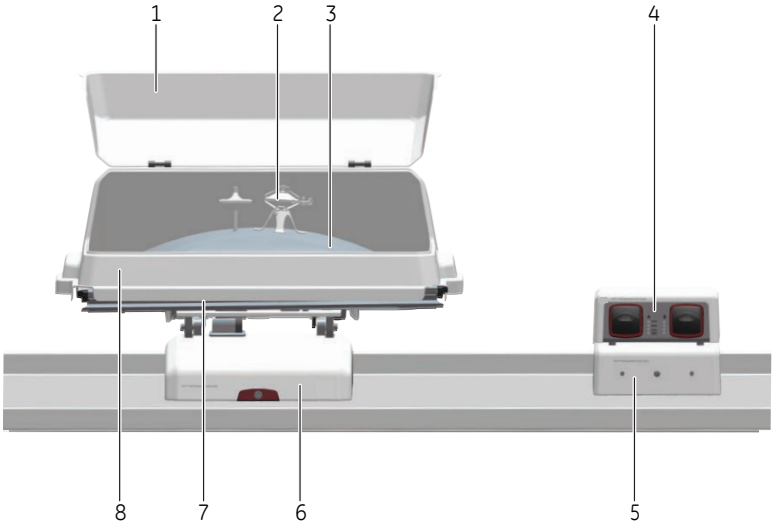
Manuals included with the system

The following manuals are delivered together with the system.

Code no.	Manual
29064612	Xuri Cell Expansion System W25 Operating Instructions
29087822	Xuri Cell Expansion System W25 Cue Card
29064922	Xuri Cell Expansion System W25 User Documentation CD

Illustration of the system

The illustration below shows the main system units for use in single mode with one Xuri Cell Expansion System W25 Pump. Dual mode uses two Xuri Cell Expansion System W25 CBCU units for controlling the two Cellbag™ bioreactors independently. Both single and dual modes can support up to three Xuri Cell Expansion System W25 Pump units.



Part	Description
1	Hatch
2	Filter heater
3	Cellbag bioreactor
4	Xuri Cell Expansion System W25 Pump
5	Xuri Cell Expansion System W25 CBCU
6	Xuri Cell Expansion System W25, rocker
7	Tray
8	Lid

2 System specifications

Product list

Code number	Description
29064568	Xuri Cell Expansion System W25, rocker
29064571	Xuri Cell Expansion System W25 Pump
29064602	Xuri Cell Expansion System W25 CBCU Full
29064600	Xuri Cell Expansion System W25 CBCU pH
29064599	Xuri Cell Expansion System W25 CBCU DO
29065252	Filter Heater
29065231	Tray 10
29065232	Tray 20
29065233	Tray 50
29065234	Lid 10
29065235	Lid 20
29065237	Lid 50

General specifications

The table below lists the system specifications of Xuri Cell Expansion System W25.

Parameter	Data
System configuration	Benchtop system, external computer
Control system	UNICORN™ 7.x
Rocker embedded PC operating system	Windows 10
Connection between PC and instrument	Ethernet
Power supply	100-120/200-240 V ~, 50-60 Hz
Power consumption	Maximum 1500 VA
Enclosure protective class	IP 21

Parameter	Data
External air supply (per CBCU)	1.0 to 1.5 bar Normal use: 1.3 L/min Fast fill: 3.5 L/min
External CO_2 supply (per CBCU)	1.0 to 1.5 bar Normal use: 0.2 L/min Fast fill: 0.5 L/min
External O_2 supply (per CBCU)	1.0 to 1.5 bar Normal use: 0.7 L/min Fast fill: 1.7 L/min
Operating ambient temperature range	15°C to 32°C
Operating humidity range	20% to 80% relative humidity (non-condensing)

Technical specifications

For detailed technical specifications, refer to the data file (code no. 29061852) available on *cytiva.com/xuri*.

3 Material conformity

Materials of construction

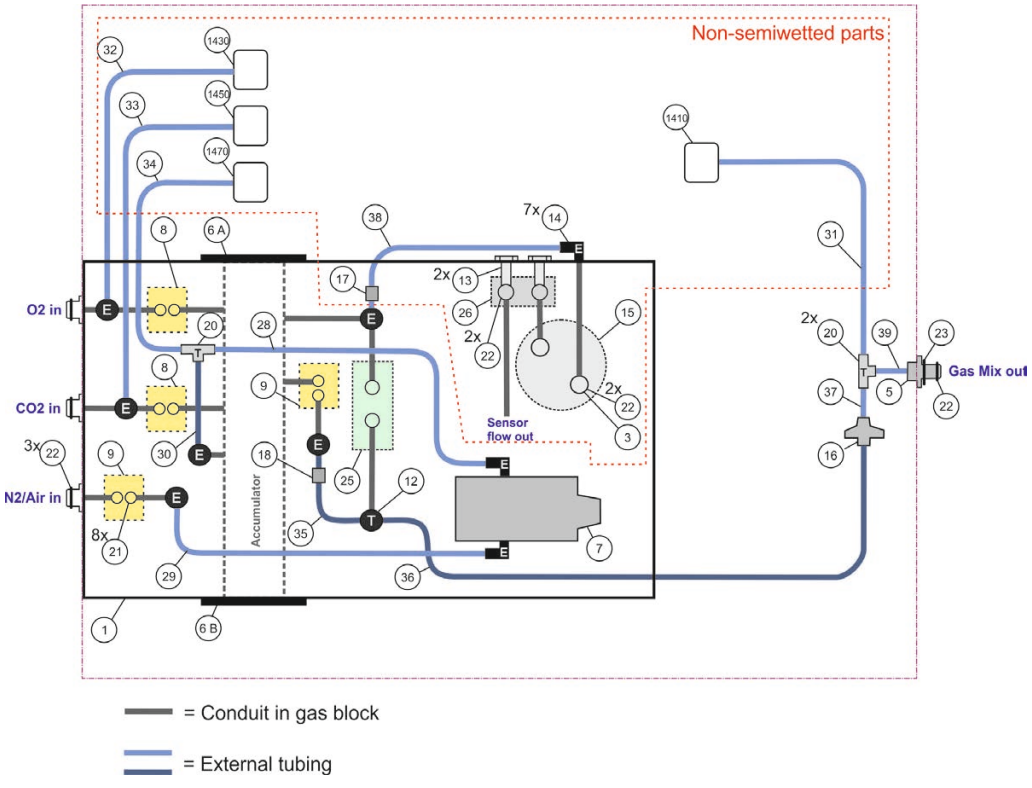
The Xuri Cell Expansion System W25 does not contain any wetted parts, i.e. no parts come into contact with the cell culture media.

In this context, semi-wetted parts are parts that are in contact with gas that is introduced into the Cellbag bioreactor.

CBCU flow chart

The following illustration shows an overview of the flow between different components in the CBCU. Components within the red dotted section of the flow chart below do not carry gas into the Cellbag bioreactor and are therefore not regarded as semi-wetted.

The semi-wetted parts of the CBCU are described in the table below the illustration.



The part numbers in the table below correspond to the circled numbers in the illustration above.

Part	Component	Material
1	Gas block	Aluminum EN AW-6082 (AlSi1MgMn)

Part	Component	Material
5	Mix out connector	ASTM 316L M (high corrosion resistant stainless steel)
6 A, B	Gaskets	EPDM 50 Shore (black)
7	Pressure regulator	Body: Aluminium Diaphragm and valve assembly: Brass / Nitrile Seals: Nitrile Springs: Steel
8	Proportional valve	360 HO2 Brass
9	Digital solenoid valve	360 HO2 Brass FKM
12	Swivel fitting, elbow	Housing and barb: Polyamide O-ring: Buna-N
14	Swivel fitting, elbow	Housing and barb: Polyamide O-ring: Buna-N
16	Check valve	Body: Polypropylene Diaphragm: Viton™
18	Insert flow restrictor	303/316 stainless steel
20	Tee	Polyamide
21-23	O-rings	EPDM
25	Mass flow regulator	Body: aluminium, Si, SiOx, epoxy Sealing: Viton
28-30	Tubing	Platinum cured Silicone
35-37	Tubing	Platinum cured Silicone
39	Tubing	Platinum cured Silicone

TSE Statement

[redacted]

TSE Statement

Xuri™ Cell Expansion System W25, Code No. 29-0645-68, includes the CBCU unit designed to supply the Cellbag™ with a gas mixture for inflation, supply of oxygen, pH control and removal of gaseous waste products.

Parts in contact with gases leading into the Cellbag are classified as semi-wetted. Of the semi-wetted parts the tubings and gas block constitutes the major surface area (≥80%). The tubing is certified to fulfill 21 CFR 177, USP VI and is animal origin free.

The gas block is made of aluminum and is not covered by these requirements. However, the cutting fluids used in the manufacture of the gas block are animal origin free.

For the remaining semi-wetted parts no information is available.

A risk assessment has been performed for the remaining semi-wetted parts and it can be concluded that the TSE risk is associated with the CBCU unit is negligible.

Signature: Virve Inglis	Date: 23 October 2013
Name: Virve Inglis	Title: Regulatory support manager

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Certificate of conformance: Signature

The Quality System of Cytiva is certified according to ISO9001, and is thereby in control of the product realization process. Cytiva has a controlled process for quality assurance in selection, assessment and evaluation of supplier where strict adherence to specifications for all material is the basis.



Thomas Wallin Valid from 1 February 2014
QA Site Leader
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