

Countstar® Altair

**Designed for Daily Use in cGxP
Regulated Environments**



The Countstar Altair-Automated Cell Analysis

The Countstar® Altair

Based on the classic Trypan blue dye exclusion principle, the Countstar® Altair system incorporates a 5 mega-pixel CMOS camera with a patented “Fixed Focus” optical imaging bench. Operation is automatic and precise. Proprietary software algorithms have been designed specifically for advanced cell recognition techniques. With Altair, you can easily and accurately capture cell concentration, viability, aggregation rate, roundness, and diameter distribution information in a single run.

The Countstar® Altair complies with all the requirements of cGxP-regulated environments:

- A powerful encrypted data management capability
- Four-level user access and control
- E-signatures and log files in full compliance with FDA 21 CFR Part 11





Process Development

Process Development

Process development in the antibody production industry includes animal immunizations, cell fusions, hybridoma selection, antibody detection, cloning of cells, cell cryopreservation, and technical scale-up of production processes. The Countstar® Altair precisely and effectively detects the state of the cells during each of these processes. Fully compliant with all cGxP regulations, Altair allows you to optimize process development.



Industrial Scale

Industrial Scale

Whether the protocol is for antibodies or vaccines, a reliable and efficient procedure for monitoring cell cultures during production is necessary for optimizing yield and quality. Even small changes in production parameters can influence cell culture performance. Altair is perfectly suited for frequent batch testing of cell cultures in production.



Quality Control

Quality Control

Stem cell therapies are promising medical concepts for the 21st century. Monitoring cell concentration and cell viability during cell isolation, culturing, and re-infusion are critically important quality control steps for the entire cell treatment process. Altair provides you with FDA-compliant solutions for quality control of stem cell therapy concepts.

Countstar® Altair Automated Cell Analyzer

Technology

- All-in-one, Compact Design
- Smart, Fast and Easy-to-use

Get results in three easy steps:

1. Add sample to the Countstar slide, insert it into the Altair
2. Select an experiment protocol using the touch screen
3. View individual test results in as little as 30 seconds

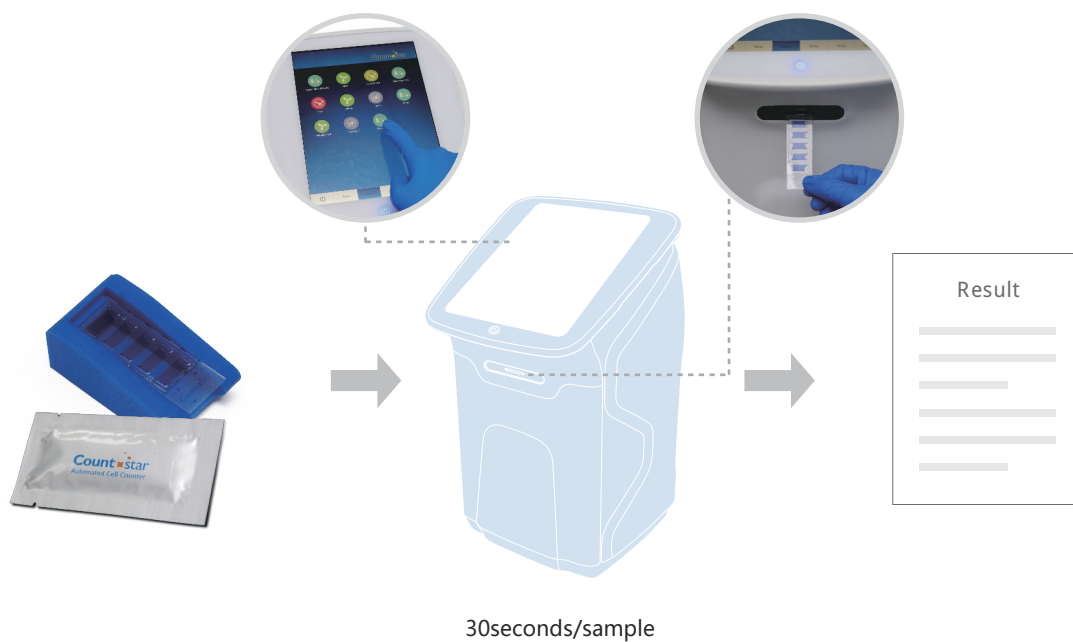


Simple

Ultra sensitive 10.4" (26.4 cm) touch screen – usable with protective gloves

High Throughput

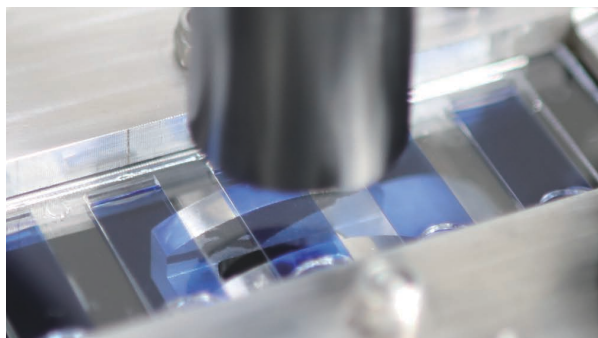
Load samples quickly using the chamber slide holder, and analyze 5 samples automatically. A single sample is analyzed in 30 seconds, or an entire 5 chamber slide in 2.5 minutes.



- **Accurate and High Reproducivity Analysis Result**

Results are highly reproducible and any interference by the operator is vanished into thin air.

Patented Fixed Focus Technology

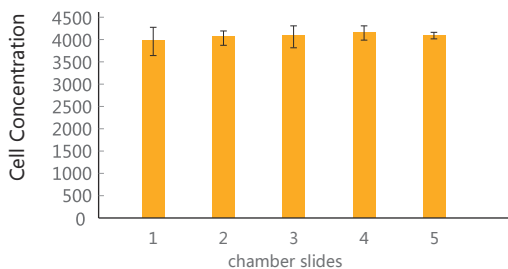


The Countstar® Altair contains an optical bench based on our "fixed focus" patent. There is no need at any time for the operator to focus when analysing samples.

Extensive observation capabilities

Up to three regions of interest are viewable in a single chamber, which allows a higher statistical accuracy for each analysis. At a cell concentration of 1.0×10^6 cells / mL, Altair automatically analyzes a total of 2,610 cells in 3 fields of interest. Compare this with a hemocytometer using 4 squares that can only capture a maximum of 400 cells.

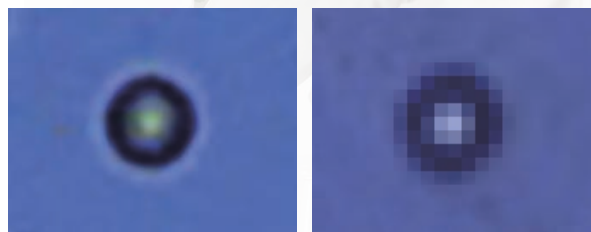
High Stability



Cell concentration result stability test between 5 chamber of one slides CV<5%

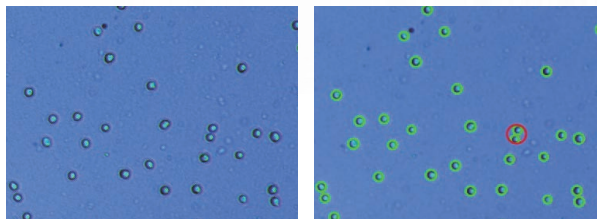
Outstanding image results

The 5 mega-pixel color camera allows users to clearly examine the native appearance of samples, and captures unrivalled morphological details of the analyzed cells.

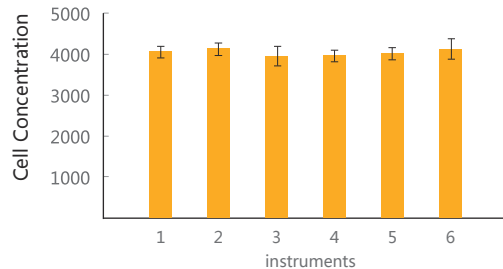


Countstar® Altair zoom in

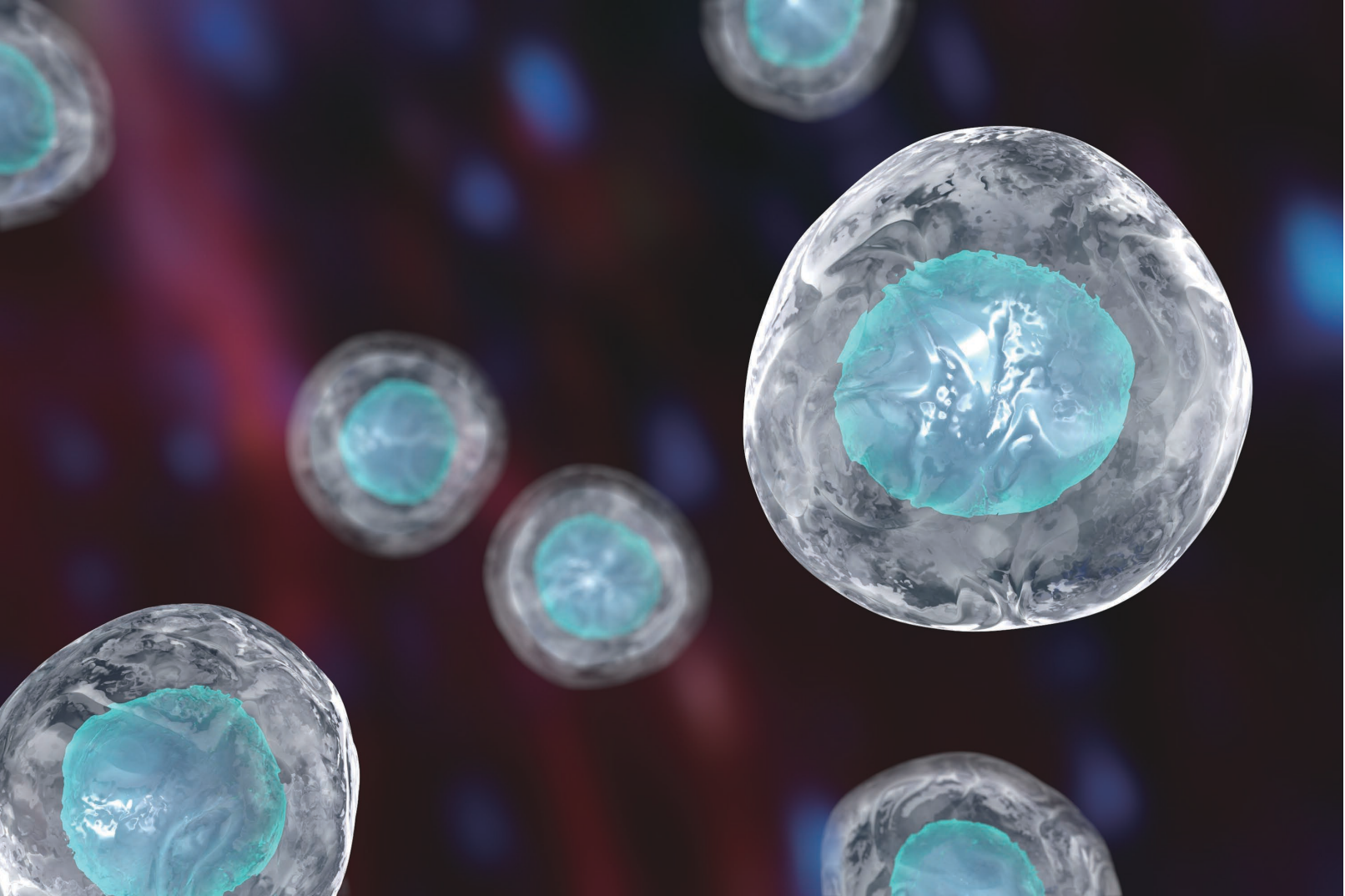
Our Protected Image Recognition Algorithms



Our protected image recognition algorithms analyze more than 20 single parameters of each classified object.



Cell concentration result stability test between 6 Countstar® Altair analysers CV<5%



- **Intuitive, Easy-to-learn and Flexible Software**

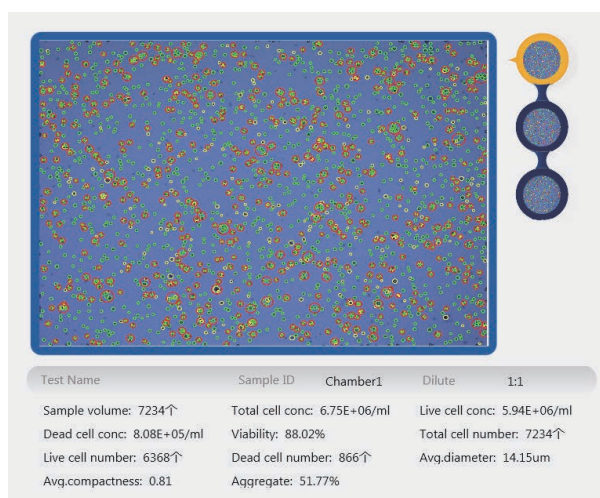
Altair is controlled with an easy to use touch screen interface with icons, similar to mobile phones and tablets. Users can modify or add steps to experiments, and personalize their experimental setups by creating their own custom icon.



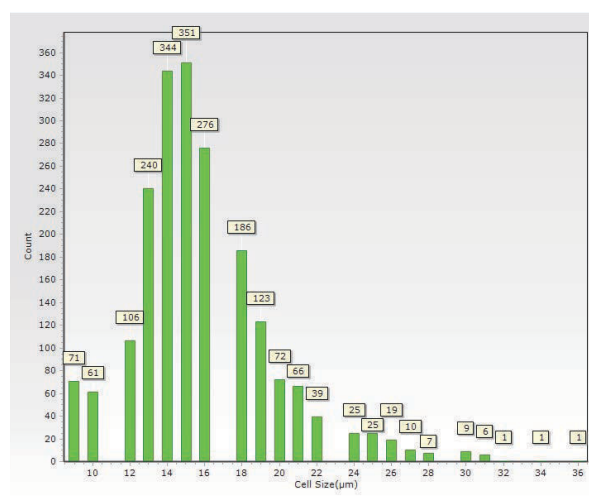
Countstar® Altair Automated Cell Analyzer

Technology

- Overview of all Experimental Results at a Glance



Overview of data



Diameter Distribution Histogram

Technical Specifications

Diameter range	3μm to 180μm
Concentration range	1×10 ⁴ to 3×10 ⁷ /ml
Objective magnification	2.5x
Imaging element	5-megapixel CMOS camera
USB	1×USB3.0 1×USB2.0
Storage	500GB
RAM	4GB
Power supply	110–230 V/AC, 50/60Hz
Screen	10.4 inch touchscreen
Weight	13kg (28lb)
Size(W×D×H)	Machine: 254×303×453mm Package: 430×370×610mm
Operating temperature	+10 °C to +40 °C
Working humidity	20% to 80%

Countstar® Altair Automated Cell Analyzer

Data Management

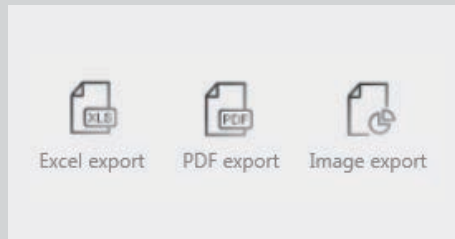
Altair uses a built-in database with a sophisticated and ergonomic design that gives the users maximum flexibility in data storage, while ensuring reliable and traceable storage of results and images.

Data Storage



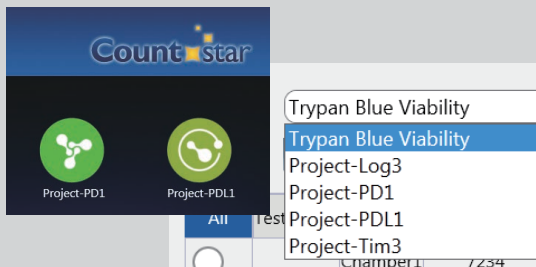
With 500GB of memory, Altair stores up to 160,000 complete sets of experimental data including images.

Data Output



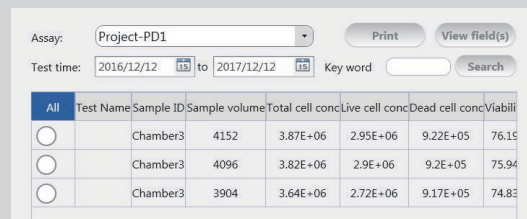
Choices for data output include PDF, MS-Excel, and JPEG files. All of which are easily exported using the included USB2.0 & 3.0 external ports.

Multi-Project Data Management



Sort data by experimental assay or project type just by assigning them to the appropriate experimental protocol. New test results will automatically be saved to the database using a pre-defined assay or project name, allowing fast and easy data organization.

Easy Retrieval



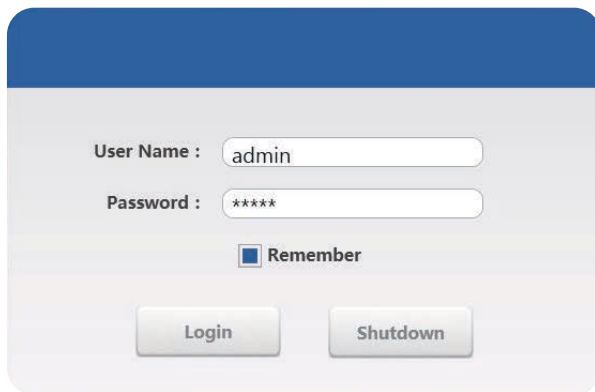
All	Test Name	Sample ID	Sample volume	Total cell conc	Live cell conc	Dead cell conc	Viability
<input type="radio"/>	Chamber3	4152	3.87E+06	2.95E+06	9.22E+05	76.15	
<input type="radio"/>	Chamber3	4096	3.82E+06	2.9E+06	9.2E+05	75.94	
<input type="radio"/>	Chamber3	3904	3.64E+06	2.72E+06	9.17E+05	74.83	

Data can be found by experiment or protocol name, analysis date, or keywords. And the retrieved data can be selected for review, print and export.

Countstar® Altair Automated Cell Analyzer

FDA 21 CFR Part11

To meet the requirements of cGxP regulated environments, Altair operates in full compliance the FDA 21 CFR Part 11 regulations.

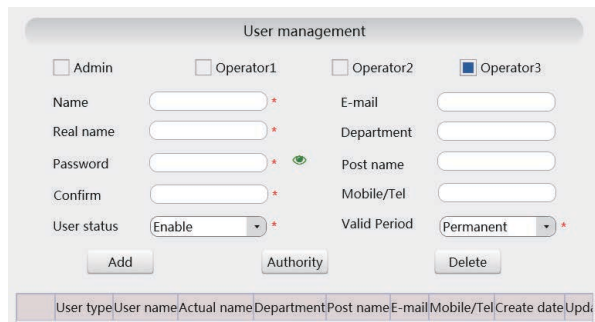


User Name :

Password :

Remember

User Login



User management

Admin Operator1 Operator2 Operator3

Name * E-mail

Real name * Department

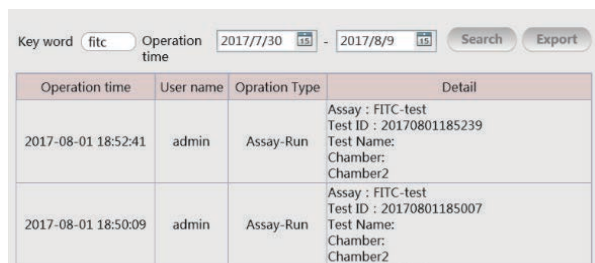
Password * Post name

Confirm * Mobile/Tel

User status * Valid Period *

User type	User name	Actual name	Department	Post name	E-mail	Mobile/Tel	Create date	Upd
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Four-level user access management



Key word Operation time -

Operation time	User name	Opration Type	Detail
2017-08-01 18:52:41	admin	Assay-Run	Assay : FITC-test Test ID : 20170801185239 Test Name: Chamber: Chamber2
2017-08-01 18:50:09	admin	Assay-Run	Assay : FITC-test Test ID : 20170801185007 Test Name: Chamber: Chamber2

E-Signatures and Log Files

Countstar® Altair Automated Cell Analyzer

Upgradable validation service (IQ/OQ) and Standard Particle Suspensions

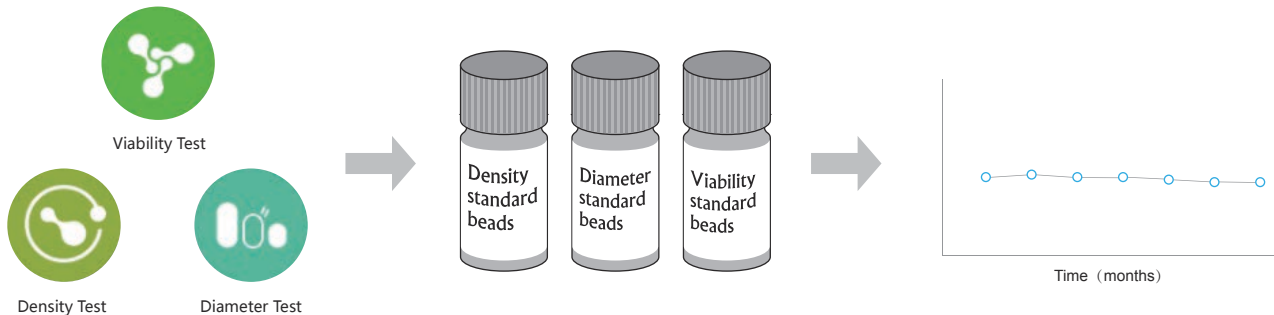
When implementing the Altair in a regulated environment, our IQ/OQ/PQ support starts early – we will meet with you if needed prior to the qualification execution.

ALIT Life Science provides the necessary verification documentation to qualify the Countstar® Altair for performing process development and production tasks in cGxP related environments.

Our QA department has established a comprehensive infrastructure in-house to comply with cGAMP (Good Automation Manufacturing Practice) guidelines for manufacturing analyzers, starting from the instrument and software design process through the final factory acceptance tests for systems and consumables. We guarantee a successful verification (IQ, OQ) on site, and we will assist in the PQ process.



Instrument Stability Test (IST)



ALIT Life Science has established a comprehensive validation plan for testing the stability and accuracy of Altair measurements in order to guarantee precise and reproducible measurement data is captured daily.

Our proprietary IST monitoring program (Instrument Stability Test) is your assurance that our instruments will meet the standards required in cGxP regulated environments. The IST will prove and, if necessary, re-calibrate the instrument in a defined cycle of time to guarantee the results measured by the Countstar® Altair remain accurate and stable during the entire life cycle of use.



Density Standard Beads

- Used to re-calibrate the accuracy and precision of concentration measurements to verify the quality of everyday measurements.
- It is also a mandatory tool for the harmonization and comparison between several Countstar® Altair instruments and samples.
- 3 different standard of Density Standard Beads are available: $5 \times 10^5/\text{ml}$ 、 $2 \times 10^6/\text{ml}$ 、 $5 \times 10^6/\text{ml}$.

Diameter Standard Beads

- Used to re-calibrate the diameter analysis of objects.
- Proves the accuracy and stability of this analysis feature. Demonstrates the comparability of results between different Countstar® Altair instruments and samples.
- 2 different standard of Diameter Standard Beads are available: $8 \mu\text{m}$ and $20 \mu\text{m}$.

Viability Standard Beads

- Used to simulate various levels of cell containing samples.
- Verifies the accuracy and reproducibility of live / dead labelling. Proves the comparability between different Countstar® Altair instruments and samples.
- 4 different standard of Viability Standard Beads are available: 25%、50%、75%、100%.

Installation Qualification Procedure (IQ)	
Disclaimer	The Countstar® FL system is for life science research only. It is not intended for use in diagnostic procedures.
About this Document	This document is to be used to perform an Installation Qualification on Countstar® FL system. This qualification covers only the Countstar® FL instrument as defined under system information and does not cover the complete automation environment.
Documentation of Deviations	All deviations occurring during this qualification procedure must be logged into the Deviation log.
Countstar® FL	
Installation Qualification Procedure	
General Information	
Customer Information	
Company:	
Address:	
System Location and Department:	
Contact Person:	

Operational Qualification Procedure (OQ)	
Operational Qualification Procedure	
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Disclaimer: The information shown above may underlie changes, and not guarantee for the correctness of the information shown above. The Countstar Altair system has at the moment no approval as medical device, and cannot be used as IVD tool.