



Frequently Asked Questions - FAQ

AppliFlex ST 500 mL & 3L

Frequently Asked Questions

AppliFlex ST

AppliFlex ST bioreactors

If I already have a my-Control with miniBio 500 ml; which components could I re-use in order to use this my-Control for a AppliFlex ST 500 ml?

Go to sharepoint and look for the retrofit document for AppliFlex ST. This documents explains which parts and consumbles and what service work is required to convert an existing my-Control setup to an AppliFlex ST setup.

How can I get my own AppliFlex ST bioreactor configured?

There are a lot of options available to configure the AppliFlex ST to your wishes. To help facilitate this configuration of your bioreactor we have created a questionnaire. Following the questionnaire we have a dialogue on what is possible and how we are going to build your ideal Single Use bioreactor.

Can I re-use my AppliFlex ST more than once?

No, since the sterility is comprised and the AppliFlex ST can't be sterilized again.

How to avoid risk of contamination with reusable sensors?

After a run the reusable sensors should be cleaned according to the sensor cleaning instructions. After autoclaving the sensors are mounted in the AppliFlex ST in a biosafety cabinet. Following this workflow the risk of contamination is minimized. The AppliFlex ST cultivation workflow can be found in the customer facing presentation.

Is the system GMP compliant?

The AppliFlex ST is a bioreactor for research and development purposes. Using it in a GMP environment requires (among other things) that all materials are traceable, we have not implemented this (yet). However, if your customer wants to validate the bioreactor in a GMP process, it depends on the risk involved. Please see the product presentation for more info or contact Applikon Biotechnology B.V.

What warranty do I get on the AppliFlex ST?

The sterility of the AppliFlex is guaranteed for two years after sterilization date.

Is the price of a customized version higher? How much?

The price of a customized AppliFlex ST is build up on two components.

1. Customization fee, this is a single fee for engineering and processing cost for a custom design.
2. The base price of a custom AppliFlex ST is higher than that of a non-customized one.

What are the running costs? Price vs glass and running costs comparison?

The running cost for an end customer of the AppliFlex ST are approximately a 40% addition to the basic price of the AppliFlex ST. These are costs for:

- pH sensor and DO sensor maintenance and replacement
- Tubing kit
- Liquid addition bottles
- Other accessories (no media costs!)

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Do you have leachables/extractables studies/reports of AppliFlex ST (can material be trusted?) What did you test and what documents do you supply?

We do not have an E&L report for the AppliFlex ST. We have verified the materials used for the manufacturing of the AppliFlex ST, this documentation is available.

How do you guarantee supplies? Is there a backup supply chain?

The AppliFlex ST is manufactured in Holland. For the production of the AppliFlex ST we only use a limited amount of the capacity available. This capacity can be expanded when there is more market demand.

Which volumes of the AppliFlex ST are available or will become available?

Currently we have a 500ml and 3L total volume AppliFlex ST. A 15L total volume reactor is under development. For sizes bigger than this we supply the Thermo Fisher HyPerforma SUB and SUF systems.

Can I combine a 3L AppliFlex ST with an ez / ez2 & my-Control?

Yes, there are bundles and add on-packs available for my-Control and ez2-Control. Retrofits packs are available for the my-Control. The retrofit pack for the ez-Control will become available soon.

Can we just throw the bioreactors in the trash? Special requirements for disposal?

In most occasions the bioreactor after use can be considered as biomedical waste. The outer packaging is carton, which can be recycled locally. The packing plastic of the AppliFlex ST is made from LD-PE (Low density Poly Ethylene) which can also be recycled locally

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Customization

What is the largest diameter impeller we can get in an AppliFlex ST 500ml?

Anything is possible with the flexibility of the 3D design. However we have to keep in mind to keep the sensors properly working at the minimal working volume. Also sparger and sample pipes should remain functional. Other than that, the limiting factor for the impeller diameter is the inner diameter of the vessel which is 73 mm.

What is the temperature range for the AppliFlex ST 500 ml?

The AppliFlex ST can be heated up to a temperature of 45°C by either the heating blanket or the Peltier heater/cooler. The Peltier heater/cooler is also capable of cooling the AppliFlex ST to 10°C below room temperature.

Can the Peltier heater/cooler of the 250 miniBio be used for the AppliFlex ST 500 ml?

No. The Peltier element are different for the 250 and 500ml since the radius of the vessel differs between these units so the 250 ml Peltier element will not fit together with the 500 ml AppliFlex ST.

What is the response time for the Peltier heater/cooler?

The heating times with a peltier heater cooler are:

Heating time	1.7 min / °C
Cooling time	2.3 min / °C

What is the delivery time of a Custom AppliFlex ST? How long does it take to make a customized version?

The total delivery time of a custom AppliFlex ST is between 8 to 12 weeks. This is a two step approach.

Step 1, making a design based on specifications and having this approved.

Step 2, production, assembly, sterilization and shipment of the AppliFlex ST

Can we weld the tubing? What materials and length is it?

All tubing which is on the headplate of the AppliFlex ST is C-Flex weldable tubing. It comes in ¼” and 1/8” Internal diameter tubing.

Is there a default configuration available for various cellines/processes?

There is a default configuration for cell culture and microbial cultures.

Are there any limits to the customization of an AppliFlex ST?

The bioreactor cannot have interfering components. This means, for example, sensors need to be submerged or impellers cannot touch any components. Also, all the connections need to be able to be places on the headplate. Other than that, there are no limitations.

Can we get a special impeller, because our cells are “special”

Yes!

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Can we make adapters which are compatible with competitor controllers and other equipment?

Yes, this will be a custom AppliFlex ST. Please supply us with information and geometry and we will assess feasibility.

Sensors for the AppliFlex

Is a RedOx sensor included with the AppliFlex ST bundles?

No. You can connect a AppliSens RedOx sensor into a AppliFlex ST cell or microbial configuration but you will need to order this separately.

Can I fit a RedOx sensor into the AppliFlex ST?

Yes that is possible however note that the AppliFlex ST cell or microbial configurations only support 2 autoclavable sensors (typically pH and dO2) so for the RedOx sensor either the pH or dO2 sensor will have to be removed. To connect everything (pH, dO2 and RedOx) please contact Applikon so we can discuss a configuration which suits this need and any other needs you might require.

Can you fit a Buglab BE2100 sensor on a 500ml AppliFlex ST?

Yes, this is possible. The sensor requires 3 cm of depth into the bioreactor, measured from the reactor wall.

Can I use a BlueSens sensor in combination with the AppliFlex ST 500 ml?

Yes, this is no problem since the BlueSens off-gas sensors are connected after the off-gas filter. The BlueSens sensors do not require anything else than a connection from the off-gas filter and a modification to the my-Control for communication.

Do you have single-use sensors?

We currently have 2 promising options for single use Sensors. We want to launch this Q1 2020.

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Applications

How does the AppliFlex ST compare to the Wave bioreactor?

The AppliFlex ST have shown to compare the same to stirred tank miniBio systems. To compare the AppliFlex ST to wave, you can compare a stirred tank to a wave bioreactor.

How to transfer a process from the micro-Matrix / shaken culture to the AppliFlex ST

There are different scaling parameters to scale from the micro-Matrix to the AppliFlex ST. Depending on the cell line a set of parameters is chosen, please contact Applikon Biotechnology for more information

Can you have simultaneous sparger + overlay gassing?

Yes, depending on the configuration

Which applications have been done by customers already?

The following cells&organisms have been grown in the AppliFlex ST.

- Vero cells
- iPSC's
- BHK
- CHO
- CAR-T cells
- Bacillus Subtilis

How is the performance of the AppliFlex ST compared to glass autoclaveable system?

We have shown that for different cell culture and microbial applications the performance of the AppliFlex ST is the same as in glass autoclavable bioreactors.

What are the advantages over competition (Eppendorf, Sartorius, Millipore)

Please look at the sales guide on SharePoint for a detailed breakdown on the differences between the systems and the advantage the AppliFlex ST offers.

How can I do (normal) sampling in the AppliFlex ST?

Please have a look at the user manual on sampling in the AppliFlex ST. The user manual can be found on SharePoint.

Can you provide successful application cases for CAR-T? What are the process settings (pH,DO etc) for CAR-T?

Yes, UCL has used the AppliFlex ST for T cell cultivation. An Application note on this and the settings can be found on SharePoint.

As I have experience in flasks and not in single-use bioreactors, how do I operate the bioreactor (parameters like pH, DO, temperature)?

Depending on your cell type and application we can give you an advice, please contact Applikon Biotechnology.