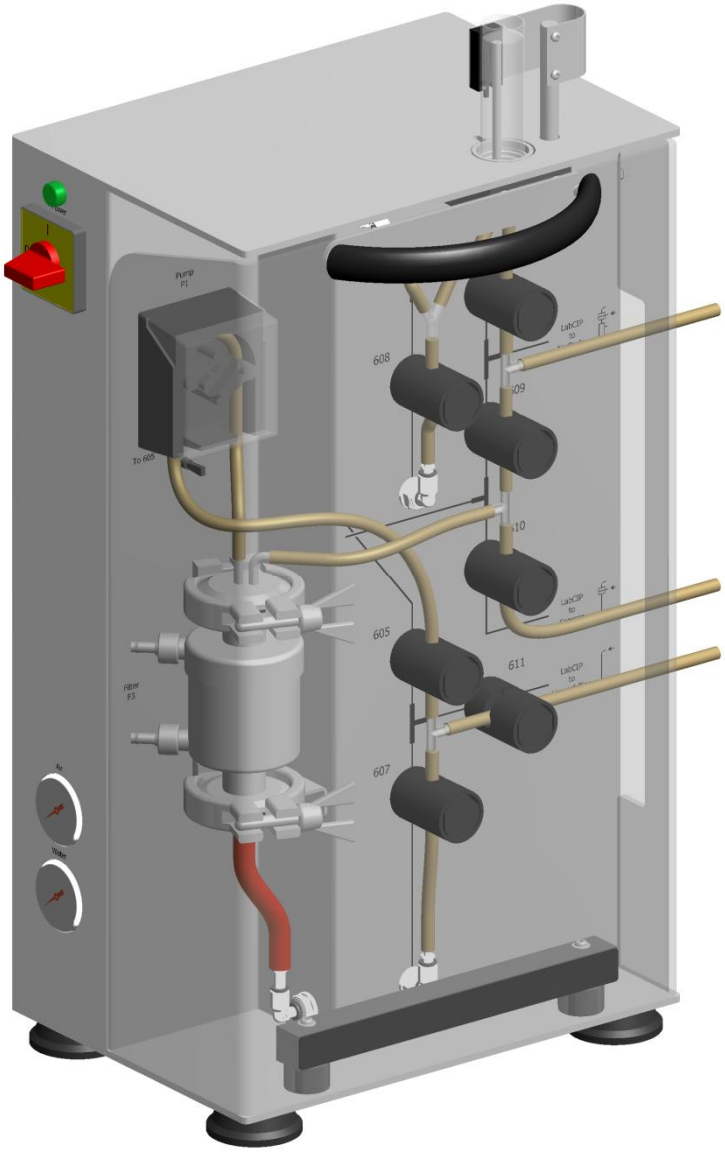
Operating Manual

LabCIP

CIP/SIP Unit



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Engineering and production in Switzerland

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1 General Information

1.1 About this Manual

This manual enables the safe and efficient handling of the equipment.

This manual is a component part of the equipment. It must be kept near to the equipment and must be accessible to the operators at all times. The operators must read thoroughly and fully understand this manual before commencement of any work.

Adhering to all the points, advice and instructions concerning safety and operation in this operating manual is a pre-condition for safe working.

Furthermore, local rules for accident prevention and general safety regulations relevant to the equipment's field of application may be in force.

This manual contains pictures which aid general understanding and can differ from the actual equipment as supplied.

NOTICE!

All information on safety, installation / commissioning, operation, maintenance and interferences of the Labfors 5 bioreactor is provided in the separate operating manual for the bioreactor.

1.2 Symbols

1.2.1 Safety Instructions

Safety instructions are labelled using symbols. All safety instructions begin with a word that signifies the degree of hazard.

Strictly follow all safety points and act with due caution to avoid accidents, damage to equipment, personal injuries and loss of property.

DANGER!

Points out an immediate, dangerous situation that leads to death or severe injuries unless avoided.

WARNING!

Points out a potentially dangerous situation that may lead to death or severe injuries unless avoided.

CAUTION!

Points out a possibly dangerous situation that leads to slight or minor injuries unless avoided.

CAUTION!

Points out a possibly dangerous situation that leads to damage to property unless avoided.

1.2.2 Hints and Recommendations

NOTICE!

Highlights useful hints and recommendations as well as information for safe and efficient use of the equipment.

1.2.3 Specific Safety Instructions

The following safety instructions are used to call attention to particular hazards.

DANGER!
Danger of fatal electric shock!
…signifies danger by electric current. Non-observance of safety instructions may lead to a severe or fatal physical injury.

WARNING!
Danger of infectious substances!
… signifies danger by infectious substances (e.g. liquids which contain bacteria or viruses). Non-observance of safety instructions may lead to serious or fatal infections.

WARNING!
Danger of corrosive chemicals!
… signifies danger by corrosive chemicals. Non-observance of safety instructions may lead to severe chemical burns to skin, human tissues and eyes.

WARNING!
Danger of hot surfaces!
… signifies danger by hot surfaces. Non-observance of safety instructions may lead to burns.

1.3 Limitation of Liability

All information and instructions in this manual comply with current standards and regulations, as well as the current state of technology & the manufacturer's knowledge and experience.

The manufacturer will not be held responsible for losses arising from:

- Non-observance of the points listed in the operating manual
- Incorrect and inappropriate use of the equipment
- Unqualified personnel using the equipment
- Arbitrary modifications
- Unauthorised technical changes
- Arbitrary repair
- Utilisation of unauthorised spare parts

The scope of delivery may differ from the explanations, descriptions and figures in this operating manual due to additional options specified on ordering and the latest technical/mechanical modifications.

Obligations stated in the delivery contract, general conditions of contract, the manufacturer's delivery conditions and the current legal regulations at the time of conclusion of the contract will apply.

1.4 Copyright Protection

1.5 Spare Parts

WARNING!
Safety risk due to incorrect spare parts!

Inappropriate or faulty spare parts may impair safety and/or may lead to damage, malfunction or complete breakdown

Therefore:

– Use only original spare parts from the manufacturer.

Spare parts may be purchased from an authorised dealer or direct from the manufacturer. See address on page 2

1.6 Terms of Guarantee

The terms of the guarantee are included in the manufacturer's general conditions of business contract to supply.

1.7 Customer Service

Our customer service is at your disposal for technical advice. See contact details on page 2.

Furthermore, our colleagues are always interested in new information and experiences resulting from user's applications for the equipment which may be valuable for the continued development of our products.

1.8 Declaration of Conformity

The equipment, as part of the LabCIP system with Labfors 5 bioreactor, conforms to the following Directive:

- EMC Directive 2004 / 108 / EC

2 Safety

This section outlines all important safety aspects for optimal personnel protection and for the safe and error-free operation of the equipment.

Non-observance of the operational descriptions and safety instructions listed in the operating manual may lead to serious hazards.

2.1 Responsibility of the Operator

The equipment is used in industrial domains, institutes and academic workplaces. Therefore an operator is individually liable with regard to statutory duties relating to operational safety.

All regulations concerning health & safety, accident prevention and environmental protection of the workplace must be complied with alongside all safety instructions in this manual. In particular:

- The operator must be informed about the current industrial safety regulations. He must carry out a risk assessment to identify additional hazards due to special working conditions related to the equipment's area of application. They must declare these hazards in the form of directives for the equipment's operation.
- The operator must ensure that these directives comply with current legal regulations and adapt them as necessary.
- The operator must clearly regulate and define responsibility for installation, operation, maintenance and cleaning.
- The operator must ensure that all employees using the equipment have read and understood the operating manual. Beyond that, he must provide training and inform personnel at regular intervals regarding potential dangers.
- The operator must provide the employees with the necessary protective equipment.

Furthermore, the operator is responsible for the equipment's maintenance in correct operational condition. Therefore, the following applies:

- The operator must ensure that the maintenance frequency, as stated in the operating manual, is adhered to.
- The operator must ensure that all safety devices are checked regularly for efficiency and integrity.

2.2 Requirements for Qualified Personnel

WARNING!
Risk of injury when used by anyone inadequately qualified!

Inappropriate use of the equipment may lead to serious physical injury and material damage.

Therefore:

– All operations must be executed by qualified personnel only.

The following qualifications for different operations are listed in the operating manual:

- **Qualified electrician**
  is capable of carrying out work on electrical systems, identifying and avoiding possible hazards independently due to their professional standing, experience, skills and knowledge of relevant standards and regulations.
  The qualified electrician is familiar with the site on which they are operating and knows the relevant standards and regulations.
- **Qualified personnel**
  are capable of carrying out the assigned work, identifying and avoiding possible hazards independently due to their professional standing, experience, skills and knowledge of relevant standards and regulations.
- **Qualified personnel in biology, biotechnology or chemical engineering**
  are capable of carrying out work in the field of biology, biotechnology or chemical engineering alongside the chemical or biological process chain due to their professional standing, experience, skills and knowledge of relevant standards and regulations.
  This includes regulations concerning health and environmental protection, safety at work, plant safety and taking quality management into account at work. They are capable of identifying and avoiding possible hazards independently. The qualified personnel in biology, biotechnology or chemical engineering are familiar with the site on which they are operating and know the relevant standards and regulations.

2.2.1 Unauthorised Persons

WARNING!
Danger for unauthorised persons!

Unauthorised persons are those who do not fulfill the criteria described here and so may not appreciate any of the dangers related to operation.

Therefore:

– Keep unauthorised people away from the area of operation.
– Challenge and remove any such persons from the area of operation, if in doubt.
– Halt operation as long as unauthorised personnel remain in the area of operation

2.3 Conventional Use of the Equipment

The equipment is designed, constructed and programmed only for conventional uses as described here.

It is used exclusively for cleaning (CIP) and sterilising (SIP) the bioreactor Labfors 5 of the equipment manufacturer.

The bioreactor system is pre-configured in the factory by the equipment manufacturer specifically for use with the equipment. Without this specific configuration, the equipment is not compatible with the bioreactor.

The key requirements for compatibility are listed as follows:

- The bioreactor system has a water temperature system.
- Only double-walled culture vessels equipped with specialist accessories such as an exit gas cooler, air pipe, harvest pipe etc. are compatible.
  The following vessel sizes (total volume) are available:
  - 2 L / 3.6 L / 7.5 L / 13 L
- The bioreactor system is configured for the use of optical sensors manufactured by Hamilton.
- The bioreactor system is configured for cultivating bacteria cultures. This means that only the stirrer shaft drive via mechanical seal is compatible.
- The bioreactor system is equipped with a mass flow controller.
- The operating software of the bioreactor system has been extended to include the CIP/SIP function.

Conventional use of the equipment also includes following all instructions in this operating manual.

Each instance of non-conventional use is considered as misuse and may lead to dangerous situations.

Safety

WARNING!
Danger due to misuse!

Misuse of the equipment may lead to dangerous situations.

In particular, do not:

- Use higher concentrations of acids/bases than indicated in the “Utilities” table in the “Technical data” chapter.
- Use other chemicals for the CIP/SIP process than the acids and bases specified in the “Utilities” table in the “Technical data” chapter.
- Change the valve settings of the CIP/SIP circuit.

All claims due to loss or damage arising from non-conventional use of the equipment will not be considered.

2.4 Personal Protective Equipment

It is essential to wear personal protective equipment to minimise health hazards

- Always wear the personal protective equipment which the particular activity requires.
- Always follow instructions available in the workplace, regarding the use of personal protective equipment

Strictly to be worn for all activities:

Protective clothes

To protect against contamination and carryover of viable organisms. Must be tight-fitting and only slightly tear proof work clothes with tight sleeves and no loose material.

Safety goggles

To protect the eyes against liquid splashes

Protective cap

To protect against contamination and carryover of viable organisms.

Protective gloves (chemical resistant)

To protect hands from aggressive substances.
Check gloves are impermeable before use. Clean gloves before taking them off and store in a well-ventilated location after use.

2.5 Particular Hazards

The following section contains additional risks which were identified on the basis of a risk assessment.

Observe all safety instructions and warning notices in this and the following sections, in order to reduce health hazards and to avoid dangerous situations.

Electric current

DANGER!
Danger of fatal electric shock!

There may be fatal danger by touching components connected to a mains power supply (single or 3-phase). Damage to insulation or components may have fatal consequences!

Therefore:

- Immediately turn off the electrical supply when the insulation is damaged and initiate a repair.
- Only qualified electricians are allowed to make these repairs on the electrical system.
- Disconnect electrical components from the mains supply and check whether it is electrically isolated before making any repairs.
- Turn off the electrical supply and lock off any isolation switch before commencing maintenance, cleaning or repairing.
- Do not bypass fuses or take them out of operation. Adhere to the correct rates (in Amps) when replacing fuses.
- Keep components which are electrically powered away from humidity, as excessive moisture may lead to short circuit.
- Do not expose equipment to inappropriate environmental temperatures outside the stated operating range.
- Never open the housing covers of the basic unit and control unit when the electrical supply is turned on.

Biohazard

WARNING!
Biohazard!

Noncompliance with biological safety regulations increases the health risk of the operator.

Therefore:

– Strictly follow all biological safety regulations.

Hot surfaces

WARNING!
Danger of scalding and burns due to contact with hot surfaces!

Skin contact with hot surfaces can lead to severe scalding and burns.

Therefore:

– Always wear protective clothes and heat resistant gloves when working near hot devices.
– Ensure that all devices are cooled down to environmental temperature before use.
– Always place a suitable notice e.g. "Hot".

Corrosive chemicals

WARNING!
Danger of chemical burns!

Non-compliance with directives and regulations concerning handling of corrosive substances and chemicals contains a high risk of chemical burns!

Therefore:

– Strictly follow directives concerning handling of corrosive substances and chemicals
– Always wear chemical-resistant gloves, safety goggles, face mask and protective clothing when working with corrosive substances and chemicals.

Dirt and materials lying about

CAUTION!
Risk of slipping due to dirt and materials lying about!

Dirt and materials lying about may lead to slipping and present a health hazard e.g. possible infection.

Therefore:

– Always keep the work place clean and tidy.
– Remove all materials not required immediately.

2.6 Environmental Protection

CAUTION!
Danger for the environment caused by mishandling!

Mishandling environmentally hazardous substances, especially incorrect disposing, may cause severe damage to the environment.

Therefore:

– Immediately take appropriate action should environmentally hazardous substances be released into the environment accidentally. Inform the responsible local authority, if in doubt.

Contaminated waste water must not be released into the environment and must be disposed of or reprocessed according to local regulations.

Chemicals such as acids and bases must be disposed of according to internal laboratory specifications and local regulations.

2.7 Adhesive Labels / Signs / Symbols

The following symbols and information labels are located in the working area. They refer to the local surrounding the area where they are applied.

WARNING!
Risk of injury by illegible symbols!

Stickers and labels can get dirty and unrecognizable by other means over the course of time.

Therefore:

– Keep all safety, warning and operating instructions in a clearly legible state.

– Replace damaged labels and stickers immediately.

Biohazards

Warns against infectious biochemical substances (e.g. liquids which contain bacteria or viruses) present in the working area.

Some procedures must be executed on objects or in rooms which contain bacteria, yeasts or other parasites. These substances may become perilous not only to medical and laboratory personnel, but also to cleaners when handled incorrectly.

Non-authorised persons must not have access to work areas in which bio hazardous or infectious materials are handled.

Immediately call a doctor if suspicion of infection arises.

Corrosive substances

Risk of chemical burns!

A chemical burn to the eyes may lead to irreparable eye injuries. Chemical burns to skin and human tissues may lead to severe injuries.

All activities involving corrosive substances must only be carried out while dressed in corrosive proof protective clothes and with corrosion proof tools or peripheral items (e.g. bottles, flasks, containers). Unauthorised persons, without corrosion proof protective clothes must not enter the working area.

Hot surfaces

Hot surfaces such as heated parts of any equipment, flasks or material and hot liquids are not always clear to see. Do not touch without protective gloves.

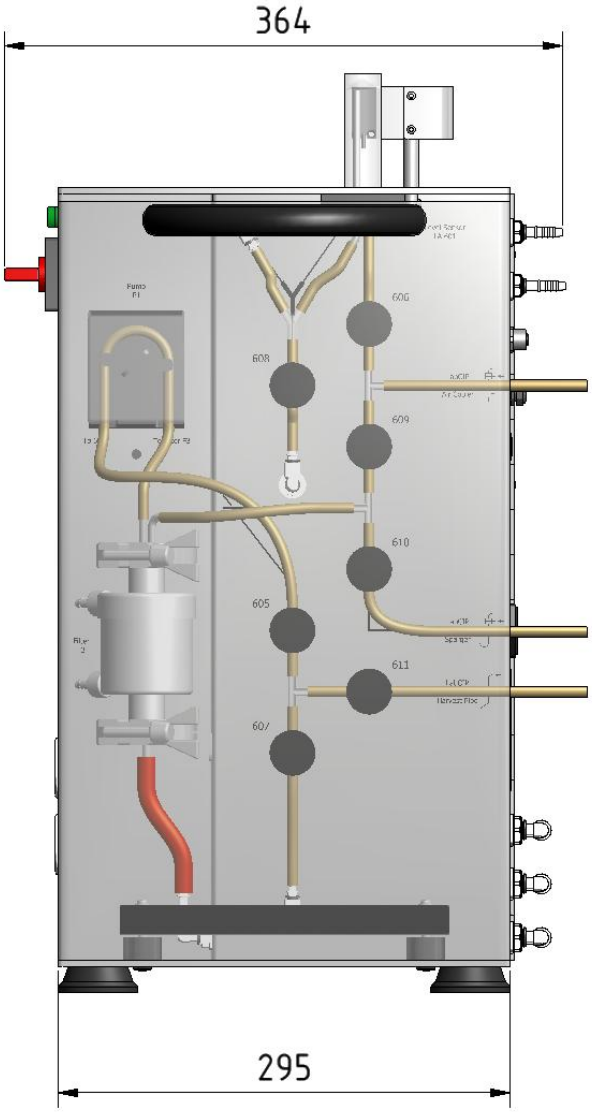
3 Technical Data

3.1 Dimensions

The following sections show the equipment and the entire system of equipment and Labfors 5 bioreactor with its dimensions.

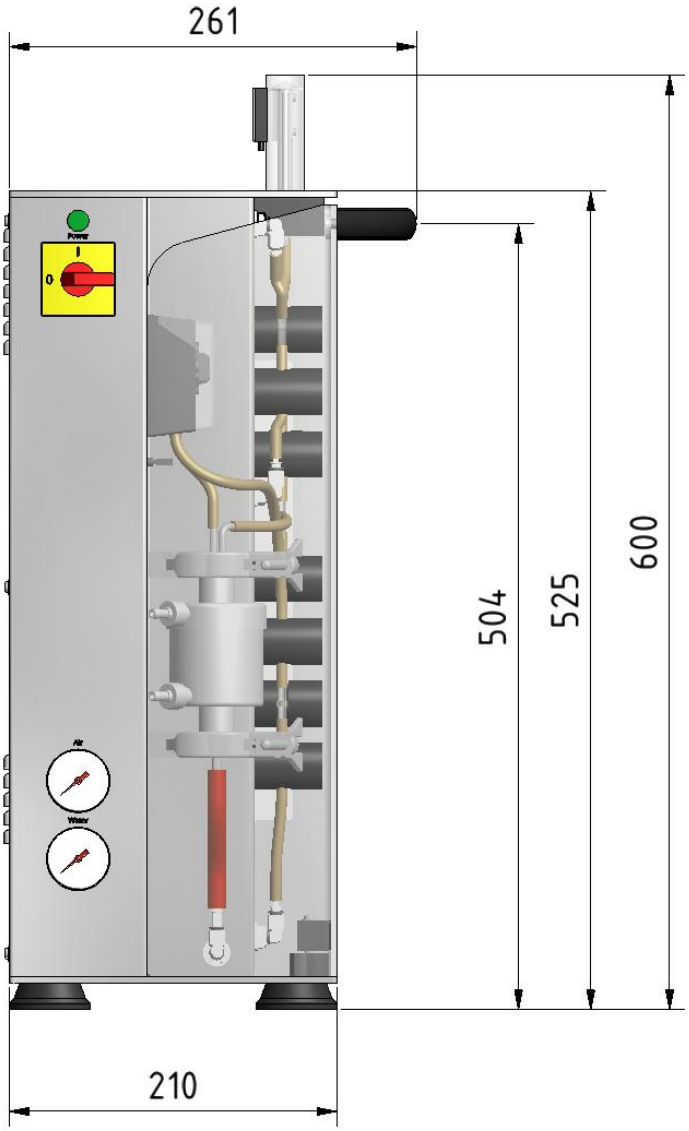
The figure of the right side view of the equipment shows the height dimensions of all connections to the equipment. These also include the interfaces, i.e. all hose and cable connections from / to the Labfors 5 bioreactor.

3.1.1 Front View



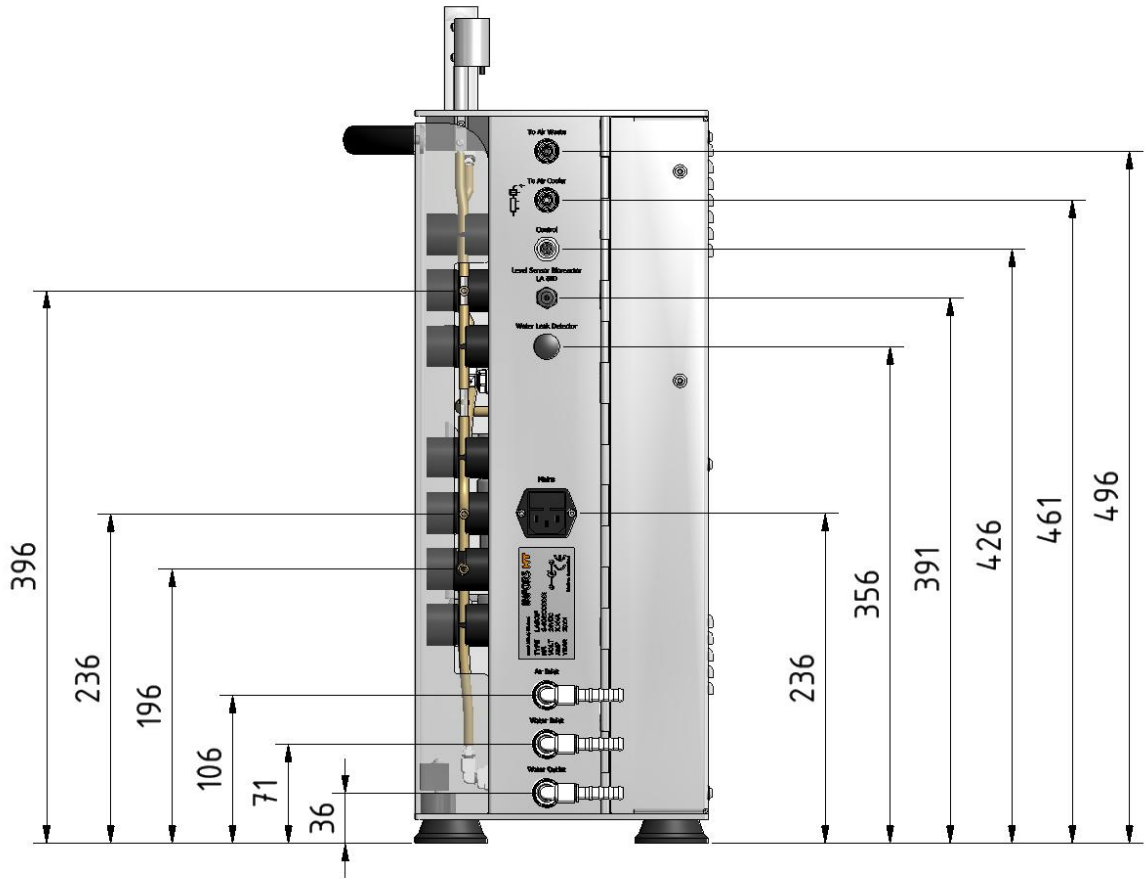
Dimensions in mm

3.1.2 Side View, Left



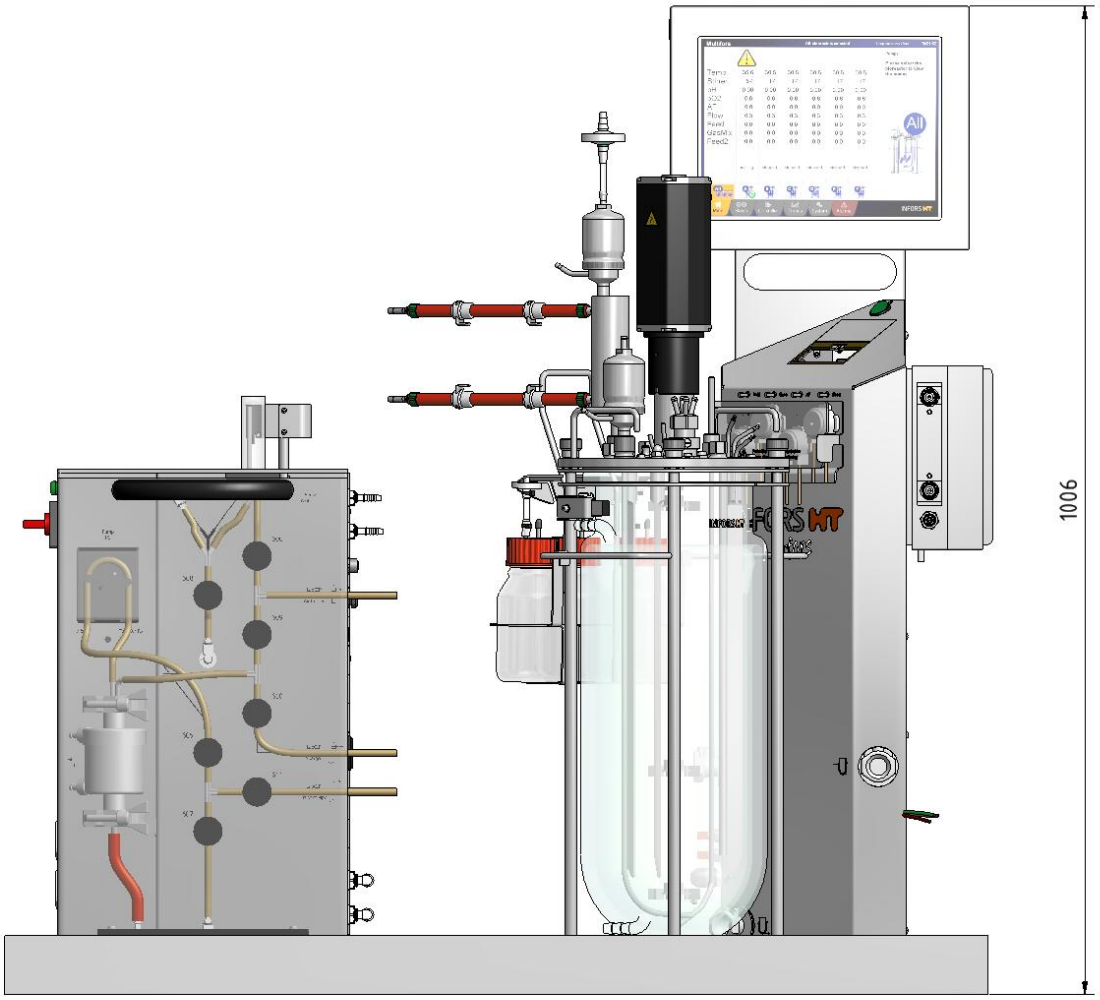
Dimensions in mm

3.1.3 Height of Connections (Right Side View)



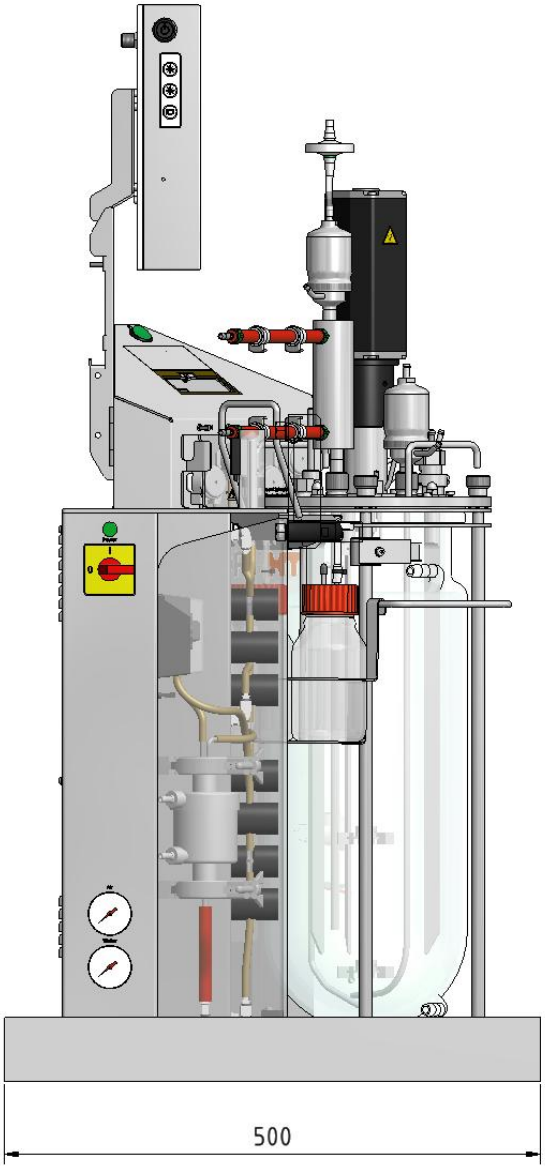
Dimensions in mm

3.1.4 Front View of the Entire LabCIP & Labfors 5 System



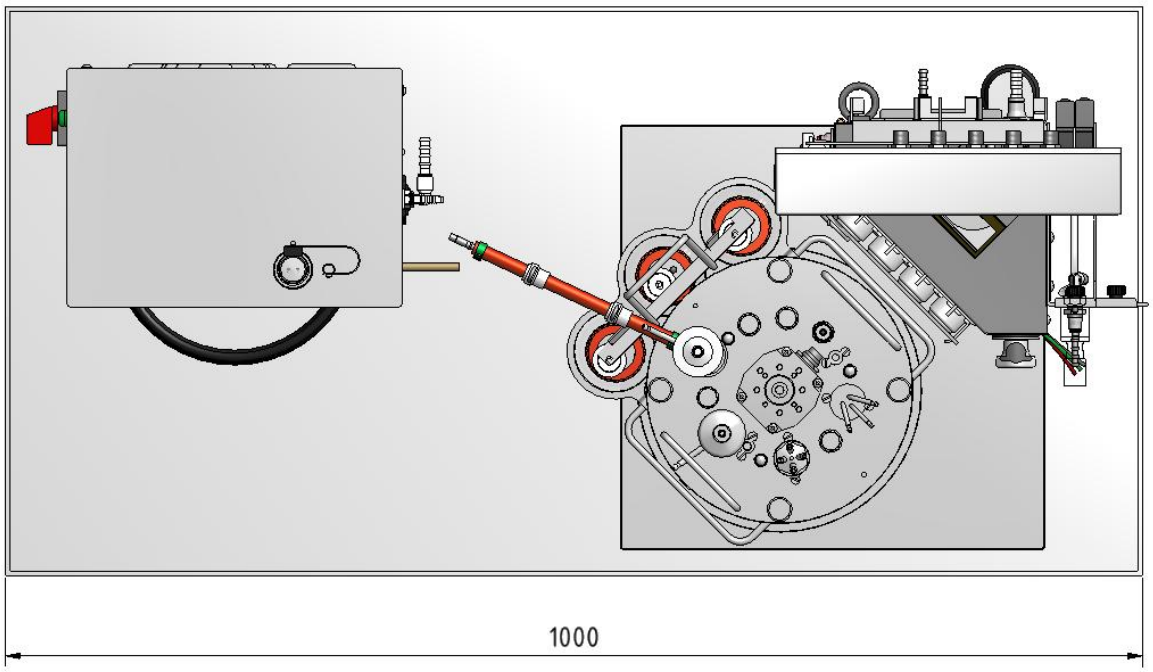
Dimensions in mm

3.1.5 Left Side View of the Entire LabCIP & Labfors 5 System



Dimensions in mm

3.1.6 Top View of the Entire LabCIP & Labfors 5 System



Dimensions in mm

3.2 Service Requirements

3.2.1 Electrical (*Mains*)

Description	Value	Unit
Voltage	115 / 230	VAC
Frequency range	50/60	Hz
Max. current consumption 115 VAC	5	A
Max. current consumption 230 VAC	2.5	A
2 fuses 5 x 20 mm, time-lag	6.3	A

3.2.2 Water Inlet (*Water Inlet*)

Description	Value	Unit
Connection pressure	2 ± 1	bar
Connection: OD of hose nozzle	10	mm
Water quality	Demineralised ≤ 1.5 mmol calcium carbonate / litre (soft)	

NOTICE!

The water quality must comply with the quality accepted for the final rinsing (process phase Final Rinse). Therefore the water must have the quality of process water.

3.2.3 Water Outlet (*Water Outlet*)

Description	Value	Unit
Connection pressure	No back pressure	
Temperature	max. 60	°C
Connection: OD of hose nozzle	10	mm

3.2.4 Air (Compressed Air) (*Air Inlet*)

Description	Value	Unit
Connection pressure	2 ± 0.5	bar
Connection: OD of hose nozzle	10	mm
Air quality	dry, clean, free of oil, grease and dust	

3.2.5 Exit gas (*To Air Waste*)

Description	Value	Unit
Connection: OD of hose nozzle	7	mm

3.3 Specifications

3.3.1 Equipment

Description	Value
Weight	20 kg
Material	■ Housing: Stainless steel ■ Door: PMMA (acrylic glass) ■ Feet: NBR (nitrile butadiene rubber)

3.3.2 Pump

Description	Value
Type	Peristaltic
Control system	Analogue
Number	1 pieces
Speed	150 rpm
Direction of rotation	Clockwise / counter clockwise (depending on the process sequence)
Hose (pump and hose tree)	■ Material: Bioprene ■ Inner diameter: 3.2 mm ■ Thickness: 1.6 mm

3.3.3 2/2 Way Hose Pinch Valves / NC

Description	Value
Control system	Electromagnetic / 24 VDC
Number	7 pieces
Valve number / function	■ **605**: CIP/SIP circuit ■ **606**: Air on and CIP/SIP venting ■ **607**: CIP/SIP emptying ■ **608**: CIP/SIP venting ■ **609**: CIP/SIP exit gas ■ **610**: CIP/SIP inlet air ■ **611**: CIP/SIP emptying

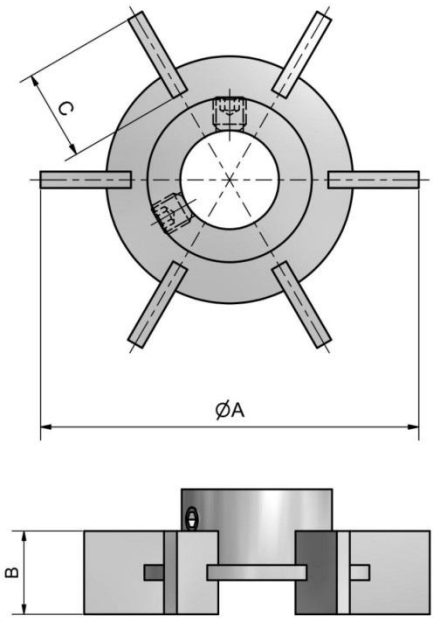
3.3.4 Water Filter

Description	Value
Type	PALL Supor® EKV membrane KA1

3.3.5 Level Sensor with Function Display

Description	Value
Use	■ Sensor **(LA600)**: level sensor, bioreactor vessel ■ Sensor **(LA601)**: level sensor, CIP/SIP circuit
Operating principle	Capacitive
Sensitivity	Adjustable
Operating temperature	-30°C to +70°C
Protection class	IP67

3.3.6 Impellers



Description	Value
Number / Type	1 Rushton impeller with 6 blades
Material	316L stainless steel, electro polished

Total Volume Vessel / Nominal Width	Dimensions		
2 l & 3,6 l / 115 mm	A = 46 mm	B = 11 mm	C = 11 mm
3,6 l & 7,5 l / 150 mm	A = 54 mm	B = 11 mm	C = 11 mm
13 l / 200 mm	A = 70 mm	B = 13 mm	C = 19 mm

3.3.7 Speed Ranges Stirrer

With standard motor

TV Vessel	DN Vessel	Range of rotation speed
2.0 L and 3.6 L	115 mm	80 up to 1500 rpm
3.6 l and 7.5 L	150 mm	80 up to 1000 rpm
13 L	200 mm	80 up to 600 rpm

With high torque motor

TV Vessel	DN Vessel	Range of rotation speed
2.0 L and 3.6 L	115 mm	10 up to 1500 rpm
3.6 l and 7.5 L	150 mm	10 up to 1500 rpm
13 L	200 mm	10 up to 1000 rpm

Legend: TV = Total volume / DN = Nominal diameter

NOTICE!

Rotation speed is valid for viscosity similar to water, without aeration. The max. adjustable rotation speed on the operating panel is set for 2 impellers. For details about rotation speed with 2 impellers see the operating manual of the bioreactor Labfors 5.

3.3.8 Option: Water Leak Detector

Description	Value
Use	For liquid detection in the drip tray
Operating principle	Capacitive
Sensitivity	Adjustable
Operating temperature	-30°C to +70°C
Protection class	IP67

3.4 Operating Conditions

Description	Value	Unit
Range of temperature	5 to 40	°C
Relative humidity, non-condensing	20 to 90	%

3.5 Emissions

Description	Value	Unit
Noise emission	<70	dB(A)

3.6 Utilities

CAUTION!
Damage due to incorrect utilities!
Using the wrong utilities may cause significant damage to property.

The acids and bases listed in the following table for acid and base rinsing and neutralisation cycles have been tested by the manufacturer and are recommended as indicated.

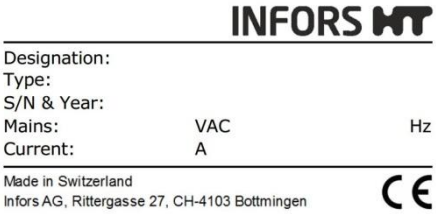
The type and degree of contamination of the culture vessel depends on the fermentation / cultivation carried out previously. This means that using other acids and bases than those recommended by the manufacturer may be meaningful and practical depending on the previous cultivation. If this is the case, their compatibility with the various materials of the equipment and culture vessel and their critical components (e.g. tubing material, seals etc.) must be established before use.

In all cases contact the manufacturer before using acids and bases not listed in the table!

Purpose of use	Recommended products
Acid for acid rinsing and neutralisation during CIP/SIP process	Citric acid min. 8 N (about 2.5 mol/L) ***OR:*** Phosphoric acid min. 8 N (about 2.5 mol/L)
Base for base rinsing and neutralisation during CIP/SIP process	Sodium hydroxide solution 8 N (8 mol/L)

3.7 Identification Plate

The identification plate is located on the right-hand side of the housing beneath the power supply connection.

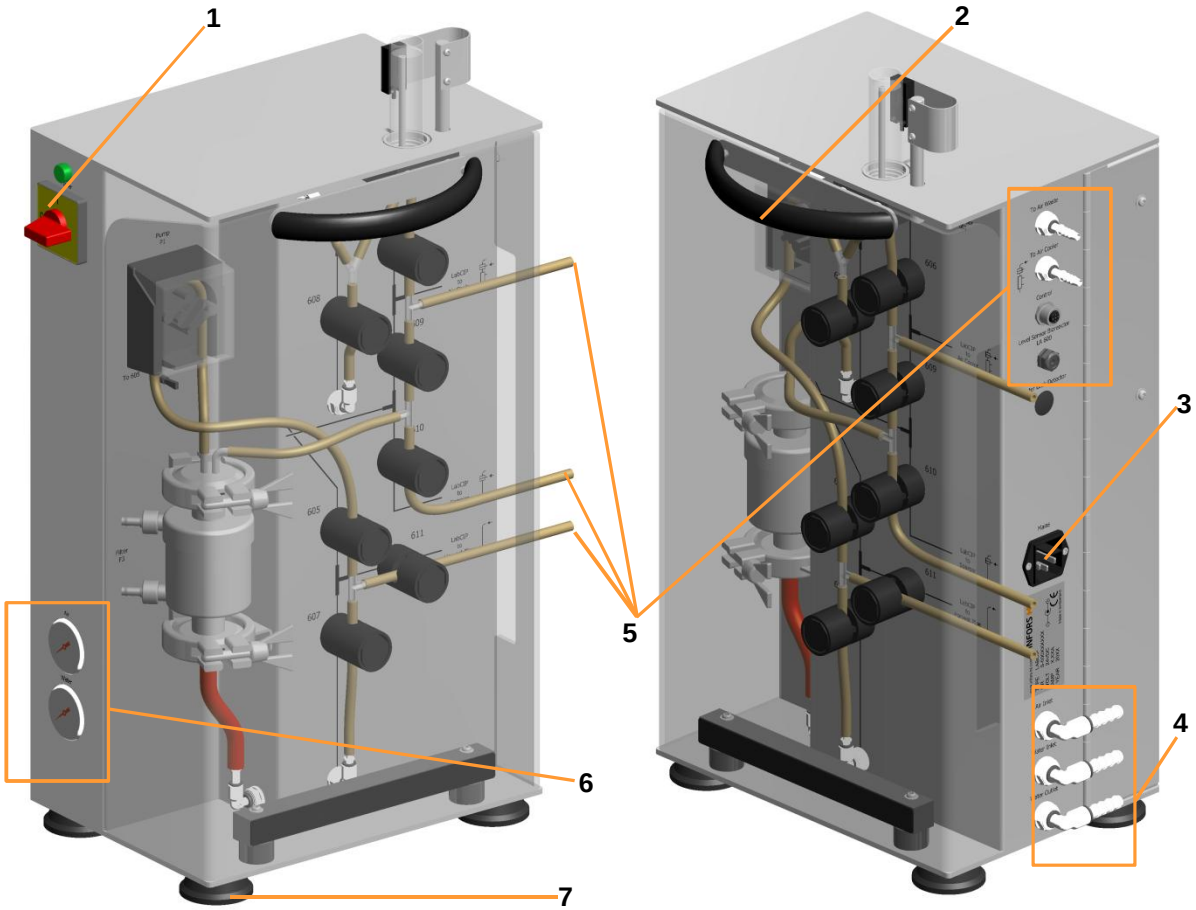


It contains the following information:

- Designation: Device designation (category)
- Type: Model/Type (Name)
- S/N: Serial number
- Year: Year of manufacture
- Mains: Nominal voltage and frequency
- Current: Current consumption
- Manufacturer address
- CE-marking

4 Setup and Function

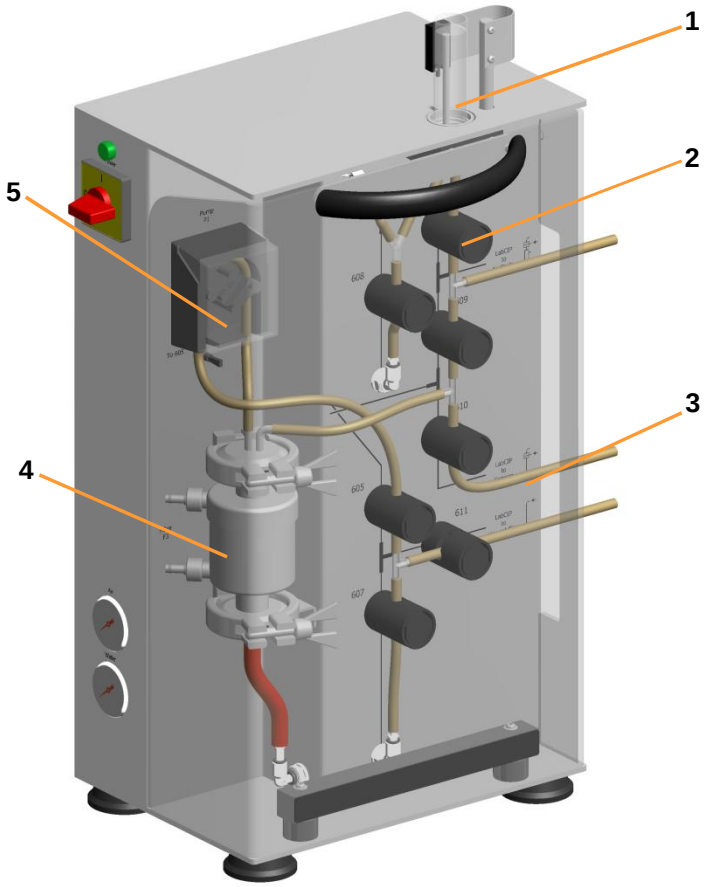
4.1 Equipment Overview



1 Main switch
2 Front door with handle
3 Mains connection
4 Water and air connections
5 Connections from / to the Labfors 5 bioreactor
6 Pressure indicator (manometer)
7 Equipment foot (4 pieces)

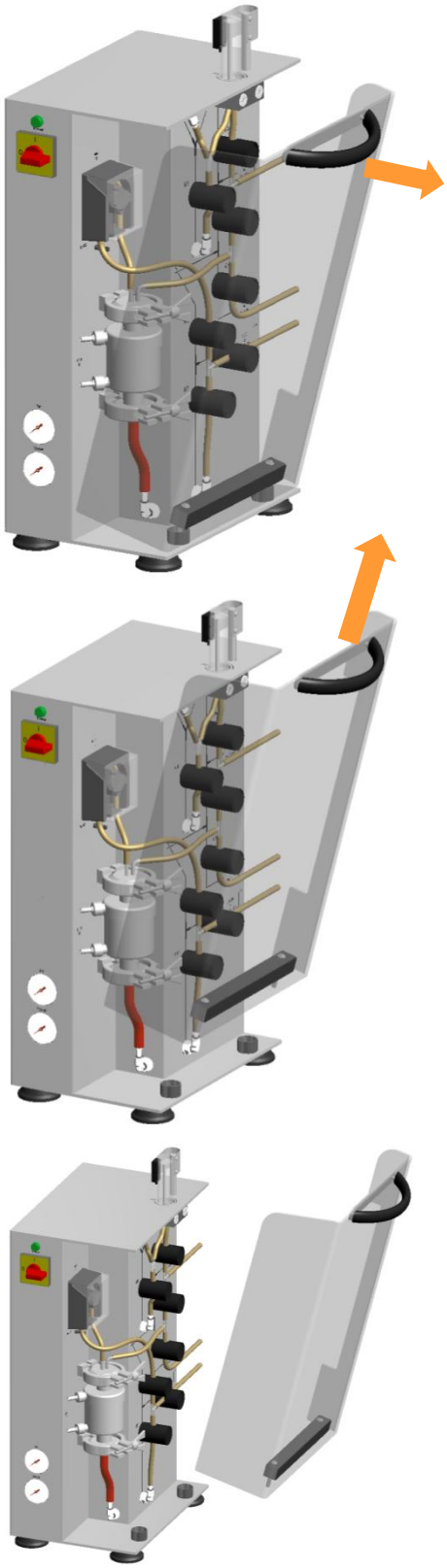
The equipment stands on four nitrile rubber feet. The equipment housing is made of stainless steel. On the left and right of the equipment there are the main switch, manometer, water, air and power connections and the various cable and hose connections for connecting with the Labfors 5 bioreactor.

Setup and Function



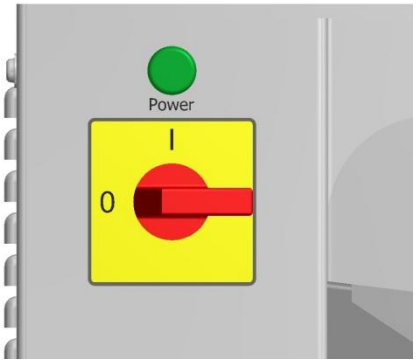
1 Circuit level sensor (LA601)
2 Hose pinch valve (7 pieces)
3 Hose tree
4 Water filter
5 Pump, peristaltic

The front door made from acrylic glass covers the different equipment components that are on the left side and front of the equipment.



The front door made from acrylic glass covers the different equipment components that are on the left side and front of the equipment.
The front door can easily be removed and re-installed (e.g. for maintenance purposes) by slightly pulling it forwards and then lifting it upwards.

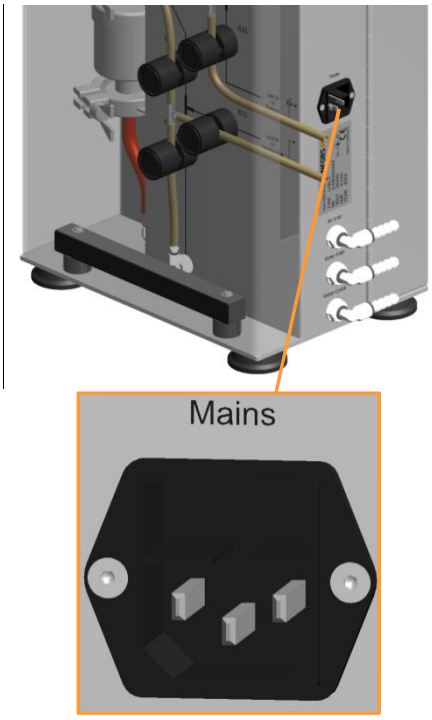
4.1.1 Main Switch



The main switch with status display is at the top on the left side of the housing.

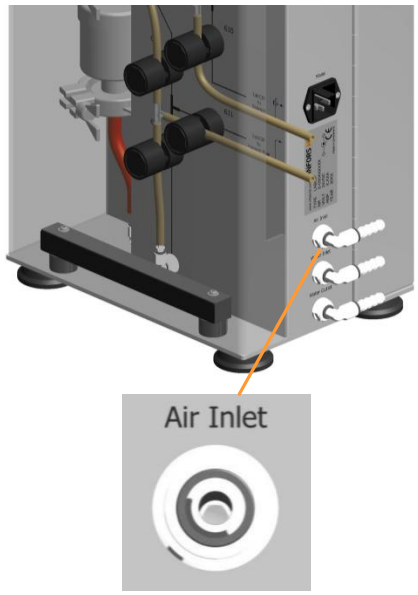
- Position **0**: Equipment is switched off, the green status display does not illuminate.
- Position **I**: Equipment is switched on, the green status display illuminates.

4.1.2 Mains Connection



The connection socket for the equipment's power cable is at the bottom of the right-hand side of the housing. It is labelled as *Mains*.

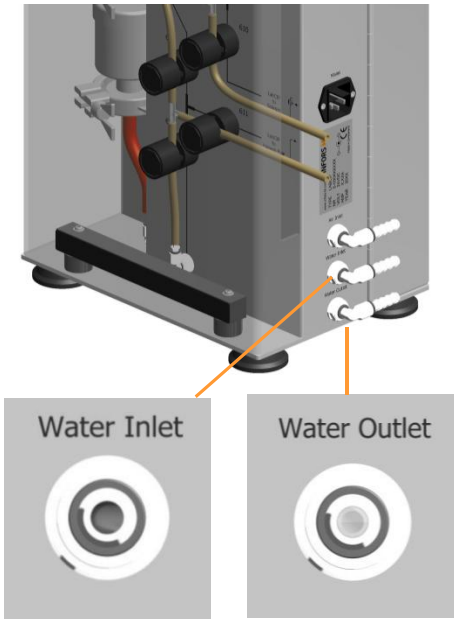
4.1.3 Compressed Air Connection



The connection with a hose nozzle for compressed air is at the bottom of the right-hand side of the housing. It is labelled as:

- *Air inlet*: (compressed air)

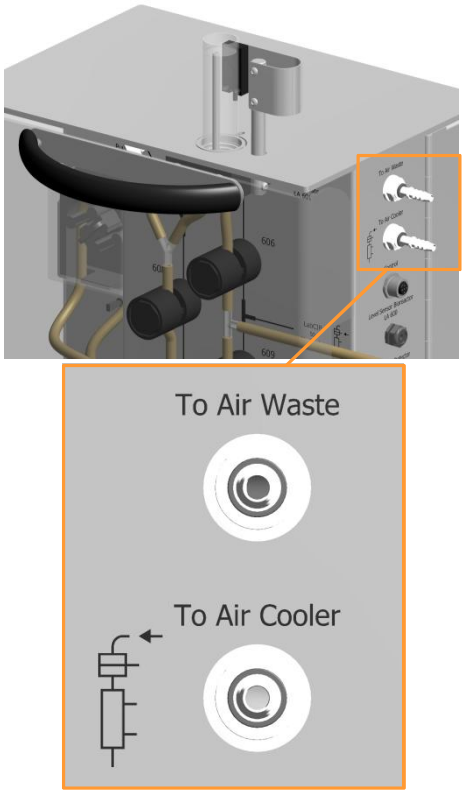
4.1.4 Water Connections



The connections with hose nozzles for the equipment's water inlet and outlet are at the bottom on the right-hand side of the housing. They are labelled as:

- *Water inlet*
- *Water outlet*

4.1.5 Connections from / to the Labfors 5 Bioreactor

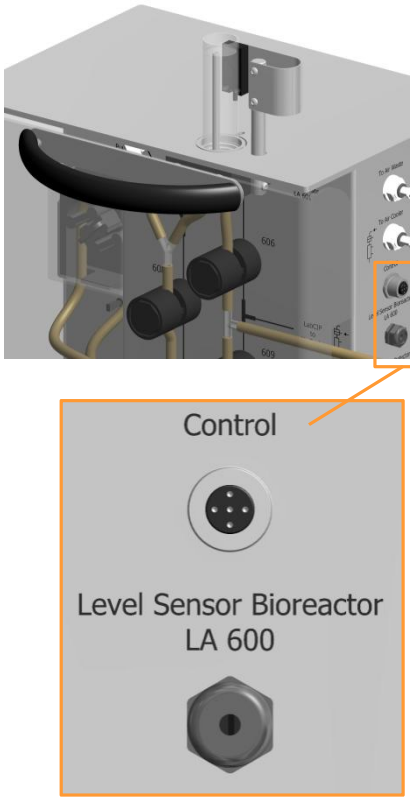


All the interfaces (hose and cable connections from / to the bioreactor are on the right-hand side of the equipment:

- *To Air Cooler* with symbol, hose nozzle and pump hose : for connecting the semi-automatic push valve exit gas cooler
- *To Air Waste* with hose nozzle and silicone hose: exit gas line

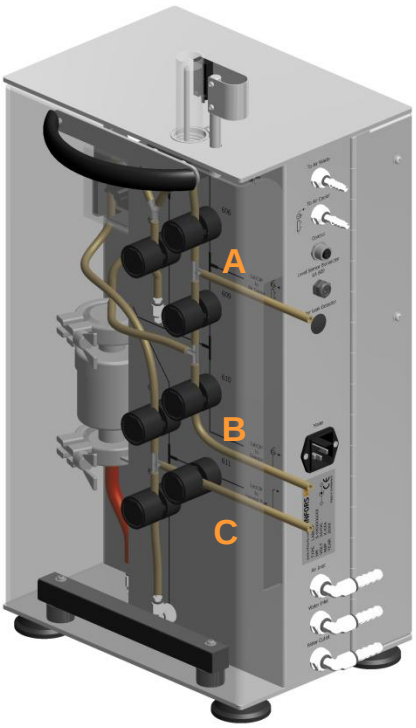
NOTIC!

The two hoses connected ex- factory are not illustrated in the left figure.

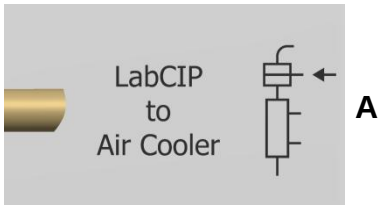


- *Level Sensor Bioreactor LA600* with cable sleeve with connecting lead (cable not shown):
  for connecting the vessel level sensor (**LA600**) of the Labfors 5 bioreactor
- *Control* with 5-pin connector socket:
  for connecting the control cable of the Labfors 5 bioreactor basic unit

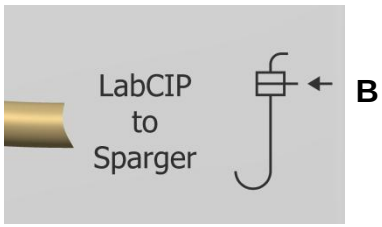
Setup and Function



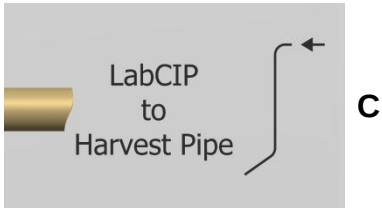
- *LabCIP to Air Cooler* (A) and symbol: Connection exit gas cooler
- *LabCIP to Sparger* (B) and symbol: Air pipe (sparger) connection
- *LabCIP to Harvest Pipe* (C) and symbol: Harvest pipe connection



A

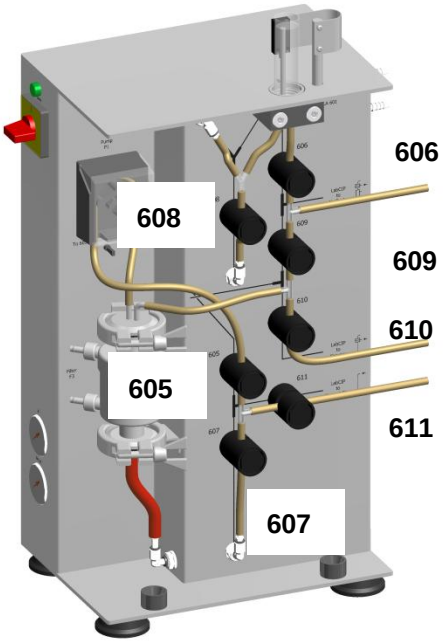


B



C

4.1.6 Hose Pinch Valves

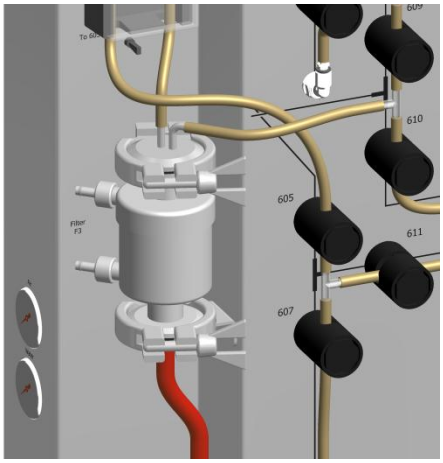


The various electromagnetically driven hose pinch valves are on the front of the equipment. They are automatically controlled during the CIP/SIP process and are all closed when switched off.

Function:

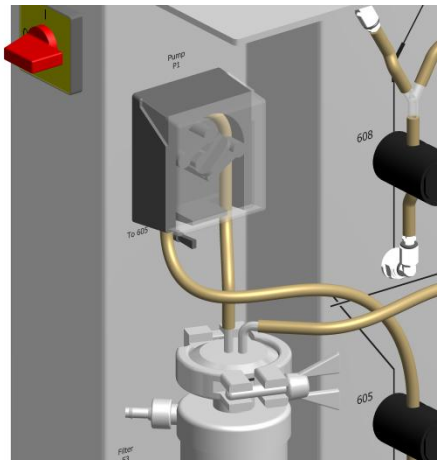
- Valve **605**: CIP/SIP circuit
- Valve **606**: Air on and CIP/SIP venting
- Valve **607**: CIP/SIP emptying
- Valve **608**: CIP/SIP venting
- Valve **609**: CIP/SIP exit gas
- Valve **610**: CIP/SIP inlet air
- Valve **611**: CIP/SIP emptying

4.1.7 Water Filter



The water is fed into the CIP/SIP circuit via a sterile filter. This is on the left-hand side of the housing. It is integrated in the hose line with clamps and flat seals and needs to be replaced regularly.
For details on the maintenance interval and the procedure see the chapter “Maintenance plan” and the chapter “Replacing the Water Filter” in the main chapter “Maintenance”.

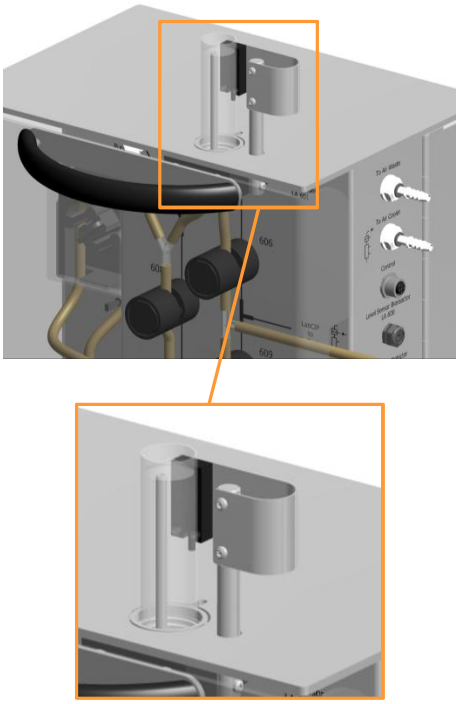
4.1.8 Pump



The left-hand side wall of the housing has the peristaltic pump for water circulation during the CIP/SIP process. The pump is driven by a stepper motor and in automatic mode rotates clockwise or counterclockwise depending on the process sequence.
The pump can also be manually activated using the rocker switcher above the pump when the equipment is switched on:

- Push and hold the rocker switch to the left:
  pump rotates anticlockwise
- Push the rocker switch to the right:
  pump rotates clockwise

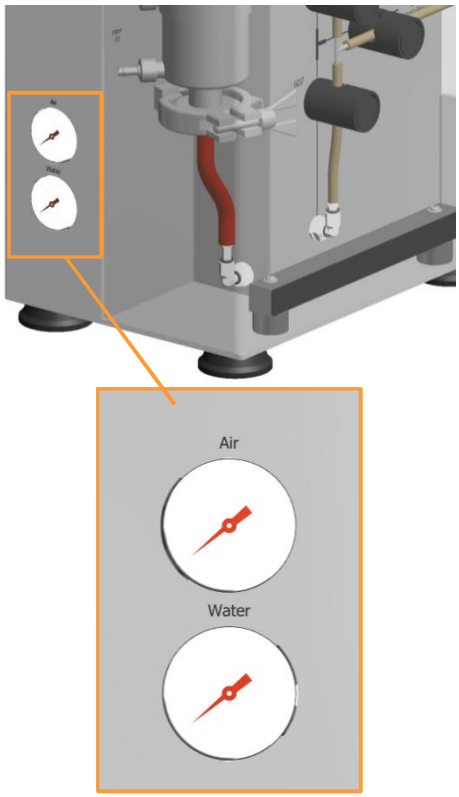
4.1.9 CIP/SIP Circuit Level Sensor (LA601)



The level sensor on the equipment (LA601) detects the level of liquid in the CIP/SIP circuit during the CIP/SIP process. It is labelled as *Level Sensor LabCIP LA601*.
The level sensor has a function display:

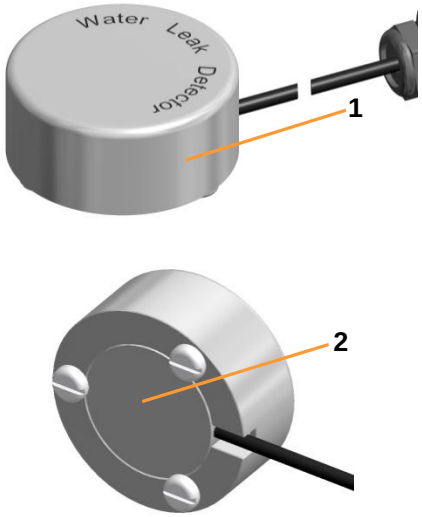
- Display illuminates: sensor does not detect any liquid
- Display light goes out: sensor detects liquid

4.1.10 Manometer



The two manometers on the left lower edge of the housing display the current pressures of air (*Air*) an water (*Water*) in the circuit during the CIP/SIP process. (Range: 0 – 2.5 bar). Pressure reducing valves are installed inside the housing. These are set to 0.5 bar ex-factory.

4.1.11 Option: Water Leak Detector (LA602)



1 Housing

2 Sensor

The optional water leak detector (LA602) is placed in the drip tray. As soon as it detects liquid, it triggers the alarm *Possible water leak detected* on the operating panel.

All valves are switched to their rest position and the process is immediately aborted.

This operating method of the detector is set at the factory for safety reasons, because the CIP/SIP process usually runs at night and without supervision.

The configuration menu offers as an alternative a setting, which triggers the alarm but does not stop the process.

NOTICE!

Refer to chapter "Submenu Global" for configuration details.

If the equipment has an optional water leak detector, it is firmly connected to the equipment. The sensor cable is located on the right side of the housing. It is labelled with *Water Leak Detector*.

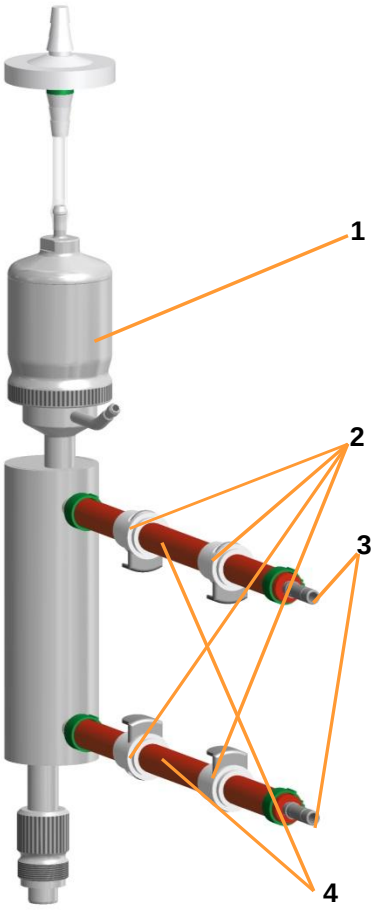
4.2 Accessories – Overview

The following accessories are part of the equipment package:

- Starter kit (for details see the chapter “Starter kit”)
- Exit gas cooler with semi-automatic push valve
- 4 inlet push valve (manual)
- Double inlet needle, D = 4 mm for 19 mm CIP/SIP ports
- 2 reagent bottles, 1000 mL
- Mounting plate pump heads
- 2 pump heads with hose, ID = 2.5 mm
- Vessel level sensor with holder
- Drip tray
- Three-way cock for Super Safe Sampler sampling system
- Air pipe (sparger) with semi-automatic push valve
- Harvest pipe
- 1 Rushton impeller
- Bottle holder for acid and base reagent bottles

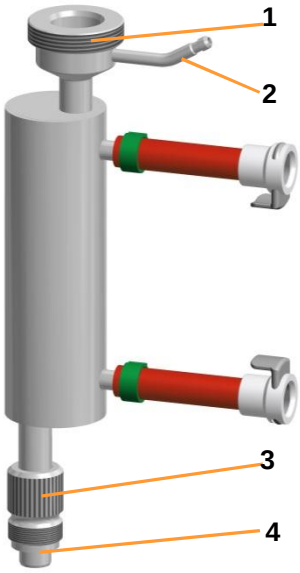
All accessories are described in detail in the following chapters.

4.2.1 Exit Gas Cooler with Semi-Automatic Push Valve



The exit gas cooler is equipped with pressure hoses for the water inlet (lower connector) and water outlet (upper connector). Suitable hoses with rapid couplings and attachable nozzles for connecting to the Labfors 5 bioreactor basic unit are supplied.

1 Semi-automatic push valve
2 Rapid coupling
3 Attachable nozzle
4 Pressure hose, D = 6 x 11.9 mm



The exit gas cooler has a fitting adapter with a stop, a hollow screw and a special threaded connection with firmly welded hose nozzle on the side.

1 Threaded connection
2 Hose nozzle
3 Hollow screw
4 Fitting adapter with stop

The exit gas cooler is fixed in the vessel top plate port using the hollow screw. The installation height is determined by the stop on the fitting adapter. The hose nozzle is for connecting to the hose tree on the equipment. The associated semi-automatic push valve is screwed onto the threaded connection.

NOTICE!

For details on the installation and connection of the exit gas cooler, see the chapter "Installing and Connecting the Exit Gas Cooler" in the main chapter "Preparations for Use".

Push valve exit gas cooler

The semi-automatic push valve for the exit gas cooler is already fitted in the factory with a compressed air hose and disposable filter.

1 Disposable filter, with green label, 0.3/1 µm, Ø = 37 for exit gas

2 Pressure hose, transparent, D = 4 x 6 mm

3 Valve piston

The semi-automatic push valve must be manually closed when preparing for the CIP/SIP process, however it is automatically opened at the end of the process. The figure on the left shows the open push valve.

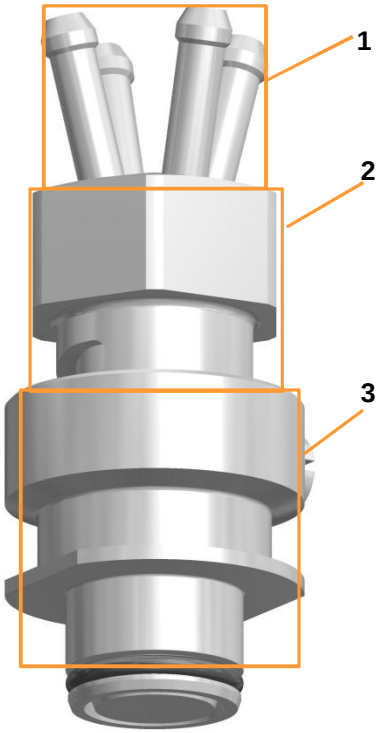
- Closing: push in the valve piston until you can see and hear it click into place
- Opening: a pressure pulse via the exit gas line during the penultimate emptying sequence at the end of the SIP/SIP process opens the push valve.

Prior to the CIP/SIP process: the (closed(!) push valve must be sterilised with hose and filter in the autoclave and then screwed on to the threaded connection on the exit gas cooler.

NOTICE!

For details on preparing the push valves see the chapter "Preparing the Air Pipe and Exit Gas Cooler Push Valves" in the main chapter "Preparations for Use".

4.2.2 4 Inlet Push Valve



The manual 4 inlet push valve is used for the sterile connection of the reagent bottles for fermentation / cultivation in the bioreactor. The 4 inlet push valve, when closed, is sterilised in the autoclave together with the reagent bottles and pump heads before the CIP/SIP process and attached to the vessel.

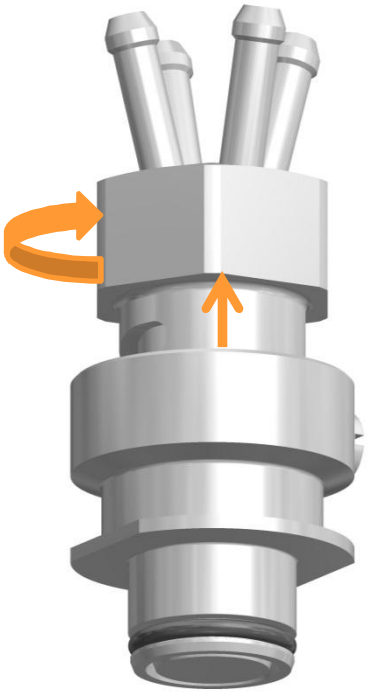
1 4 inlet connection (4 firmly welded hose nozzles)

2 Rotary piston (with visible thread)

3 Valve body

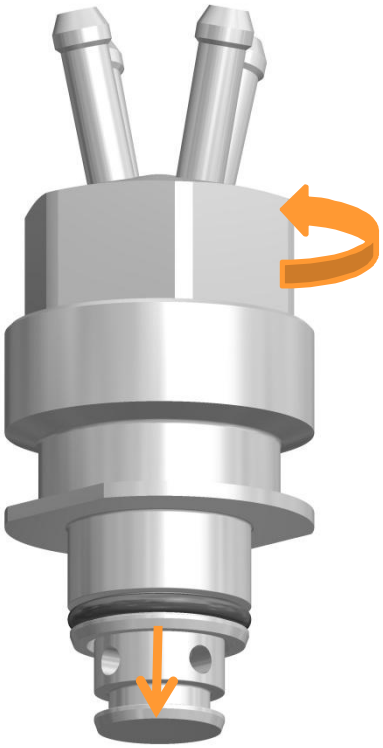
NOTICE!

For details on preparing the 4 inlet push valve and the reagent bottles, see the section “Preparing the 4 Inlet Push Valve and Reagent Bottles” in the main chapter “Preparations for Use”.



Closing the 4 inlet push valve

Turn the rotary piston counter clockwise.
The thread on the rotary piston is visible, 4 inlet connection is in the top position



Opening the 4 inlet push valve

Turn the rotary piston clockwise.
The thread on the rotary piston is no longer visible, 4 inlet connection is in the lower position, rotary piston protrudes out of the valve body.

4.2.3 Double Inlet Needle

The double inlet needle for 19 mm vessel top plate ports is used for connecting the reagent bottles with acid and base for the CIP/SIP process.

NOTICE!

For details on preparing the reagent bottles see the section “Preparing the acid and base reagent bottles”.

4.2.4 Reagent bottles for acid and base

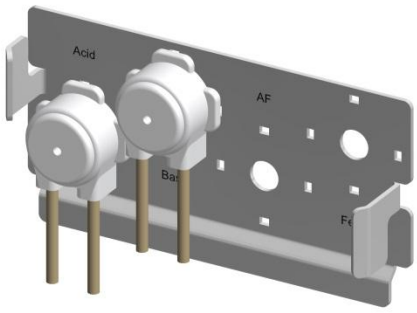
Two 1000 mL reagent bottles made from borosilicate glass are supplied for adding acid and base during the CIP/SIP process. The reagent bottles are fitted with disposable filters and silicone hoses.

1 Disposable filter

2 Cable ties, total 5 pieces

3 Silicone hose, Ø = 3 x 5 mm, hose length: 3.3 m

4.2.5 Mounting Plate with Pump Heads



The mounting plate with two attached pump heads is used for adding the acid and base during the CIP/SIP process.
The mounting plate, along with the pump heads, can be attached easily to the pump motor shafts on the Labfors 5 bioreactor basic unit.

NOTICE!

The design and handling of the mounting plate and pump heads is the same as the mounting plate and pump heads of the Labfors 5 bioreactor for adding the reagents and feed solution.

4.2.6 Vessel level sensor (LA600)

The vessel level sensor (LA600) detects the level of liquid in the vessel during the CIP/SIP process. It is provided with a cable and connector for connecting to the connection lead on the equipment.

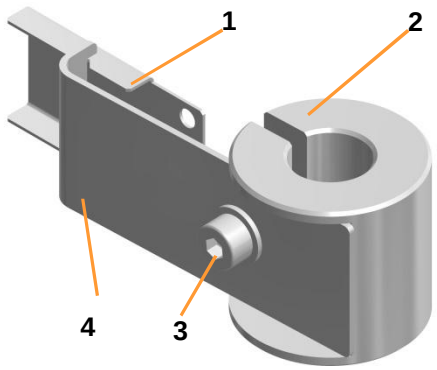
1 Connection lead and connector
2 Sensor with function display (LED)

- Function display illuminates: sensor does not detect any liquid
- Function display light goes out: sensor detects liquid

The sensitivity of the sensor is correctly pre-set in the factory of the equipment manufacturer.

NOTICE!
The sensitivity of the sensor should be checked and adjusted, if necessary, before starting the first CIP/SIP process. For details see the chapter "Adjusting the Sensitivity of the Vessel Level Sensor" of the main chapter "Maintenance".

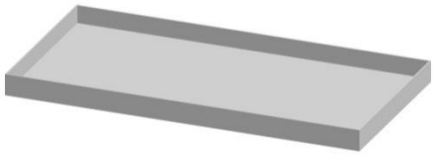
When the equipment is delivered together with the Labfors 5 bioreactor, the level sensor is pre-installed on the vessel holder using an appropriate holder. The holder consists of:



1 Positioning plate with locking mechanism
(level sensor is fixed to the positioning plate on delivery of equipment)
2 Clamping ring
3 Allen screw and washer
4 Retaining bracket

NOTICE!
For details on the correct positioning, see the chapter "Checking the Position of the Vessel Level Sensor" in the main section "Preparations for Use".

4.2.7 Drip Tray

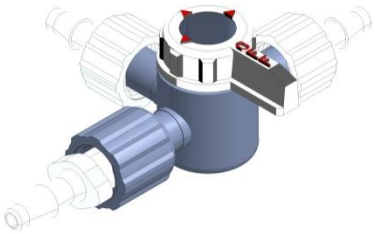


The equipment and the Labfors 5 bioreactor are placed together on a chemical-resistant drip tray made from polypropylene.
Dimensions: 500 x 1000 x 60 mm

4.2.8 Three-Way Cock for Super Safe Sampler Sampling System

Sampling during fermentation / cultivation is performed using the aseptic Super Safe Sampler sampling system via the harvest pipe. So that the sampling system can be integrated in the hose line from the harvest pipe to the equipment, a suitable connecting part is supplied.

- Three-way cock with corresponding Luer connectors



- 10 cm silicone hose, Ø = 3 x 6 mm as connecting piece between the harvest pipe and the three-way cock.

4.2.9 Air Pipe (Sparger) with Semi-Automatic Push Valve

Air pipe (sparger)

The supplied air pipe (sparger) has a fitting adapter with stop, a hollow screw and a special threaded connection with firmly welded hose nozzle on the side.

1 Hose nozzle
2 Threaded connection
3 Hollow screw
4 Fitting adapter with stop

The air pipe (sparger) is fixed in the vessel top plate port using the hollow screw. The installation height is determined by the stop on the fitting adapter. The hose nozzle is for connecting to the hose tree on the equipment. The threaded connection is needed for screwing on the associated semi-automatic push valve (see next section).

NOTICE!

For details on mounting and connection of the air pipe (sparger), see the chapters “Installing the Air Pipe (Sparger)” and “Connecting the Air Pipe (Sparger) in the main chapter “Preparations for Use”.

Setup and Function

Push valve air pipe (sparger)

The figure on the left shows an open semi-automatic push valve. The hose nozzle on the push valve is for connecting the process air/gas hose line to the bioreactor.

1 Hose nozzle

2 Valve piston

The semi-automatic push valve must be manually closed when preparing for the CIP/SIP process, however it is automatically opened at the end of the process.

- Closing: push in the valve piston until you can see and hear it click into place
- Opening: a pressure pulse via the process air line at the end CIP/SIP process opens the push valve.

Prior to the CIP/SIP process: the closed(!) push valve must be sterilised with hose and filter in the autoclave and then screwed on to the threaded connection on the air pipe (sparger).

NOTICE!

For details on preparing the push valves see the chapter “Preparing the Air Pipe and Exit Gas Cooler Push Valves” in the main chapter "Preparations for Use".

4.2.10 Harvest Pipe

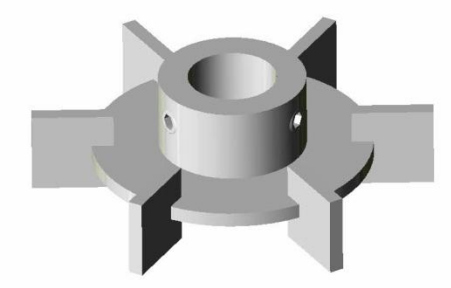
The special design of the supplied harvest pipe, when at the correct installation height, enables a complete emptying of the vessel during the various emptying sequences of the CIP/SIP process. The vessel size determines the total length of the harvest pipe.

When the equipment is delivered together with the Labfors 5 bioreactor, the harvest pipe is already installed.

NOTICE!

For details on the correct installation height and on connecting the harvest pipe, see the chapters "Checking the Installation Height of the Harvest Pipe" and "Connecting the Harvest Pipe" in the main chapter "Preparations for Use".

4.2.11 Rushton Impellers

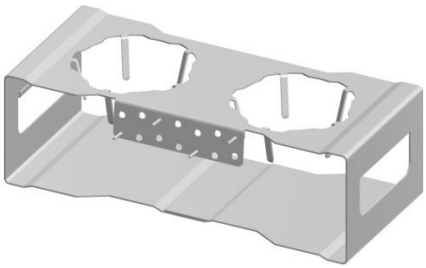


As standard, for the equipment design for bacteria of the Labfors 5 bioreactor the stirrer shafts of all vessel sizes are equipped with two Rushton impellers. For an optimal cleaning process with the equipment (LabCIP), a third impeller is required.
When the equipment is delivered together with the Labfors 5 bioreactor, all three impellers are installed and correctly positioned.

NOTICE!

For details on the impeller positioning, see the chapter “Checking the Position of the Impellers” in the main chapter “Preparations for Use”.

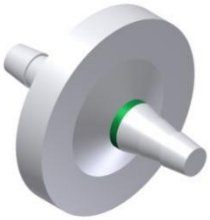
4.2.12 Bottle Holder



A bottle holder is supplied to attach the acid and base reagent bottles. On the front side of the bottle holder, the mounting plate with the pump heads can be attached.

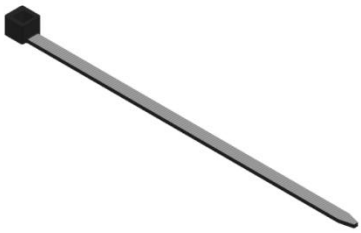
4.2.13 Starter-Kit

A starter kit is included in the package of the equipment. It contains:



- 1 disposable filter, green marking, 0.3/1 µm, Ø = 37 mm for exit gas

- 2 disposable filters, red marking, 0.2 µm, Ø = 37 mm for inlet air.



- 100 cable ties, 2.5 mm

- 6 hose clamps, INOX with screw, Ø = 14 mm for fixing the water inlet and outlet hoses

- 2 m pressure hose, red, Ø =8 x14.5 mm for water inlet and outlet
- 4 m silicone hose Ø = 2 x 6 for reagent bottles
- 1 m silicone hose Ø = 5 x 8 mm for inlet air
- 4 m silicone hose Ø = 4 x 7 mm for exit gas

4.3 Optional Accessories

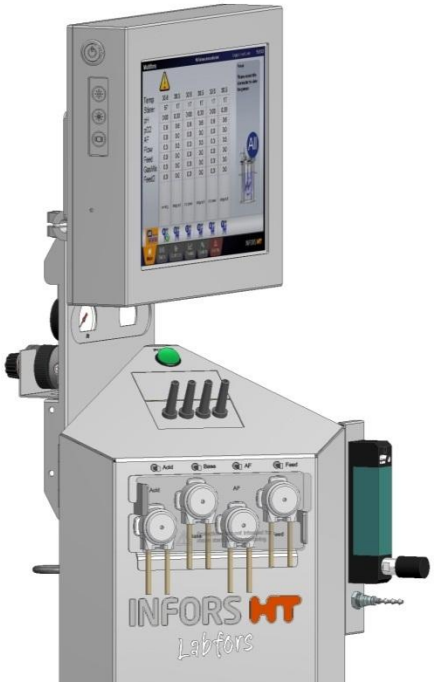
The CIP/SIP process runs automatically. Only the process preparations require a few manual procedures. For this the two semi-automatic push valves and the manual 4 inlet push valve, for example, need to be autoclaved. These components can also be obtained individually or as sets.

This makes it possible to save more time by preparing a set of push valves even during an ongoing bioprocess. In this way the bioreactor is always running in cultivation or cleaning / sterilisation mode.

NOTICE!

The sets are not included in the equipment packages and need to be ordered separately.

4.4 Operating and Control Panel, CIP/SIP Process



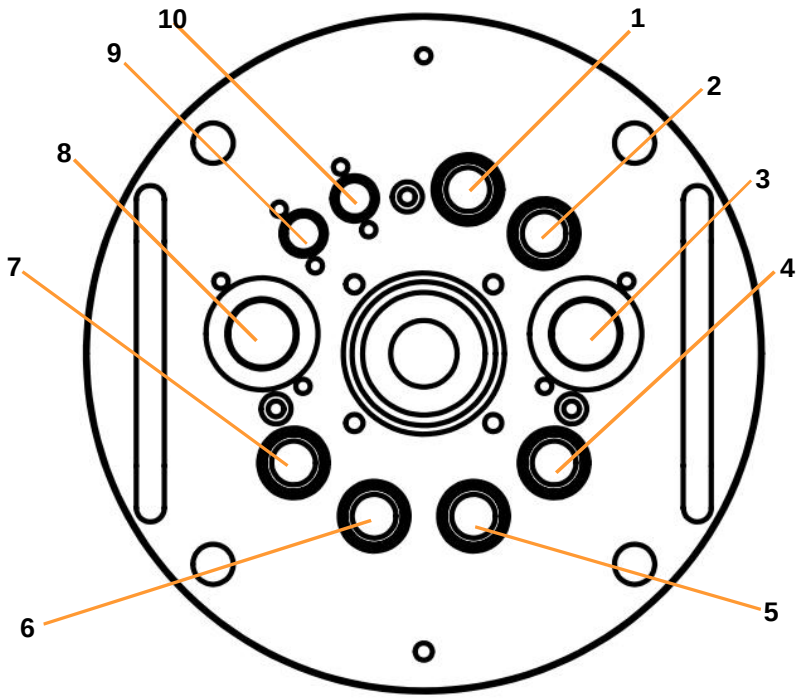
The entire CIP/SIP process is controlled using the operating panel of the Labfors 5 bioreactor. The LabCIP functions are integrated in the bioreactor software on delivery of the equipment.

NOTE!

For details on the process control system and configuration see the section "CIP/SIP process control system" in the main section "Operation".

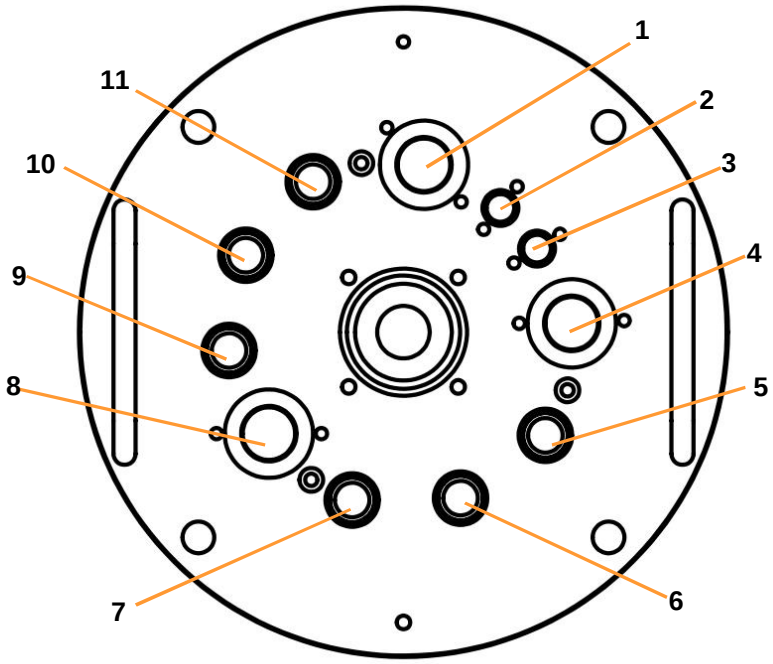
4.5 Vessel Top Plate Configuration

4.5.1 Vessel Top Plate DN 115: Ports & Configuration



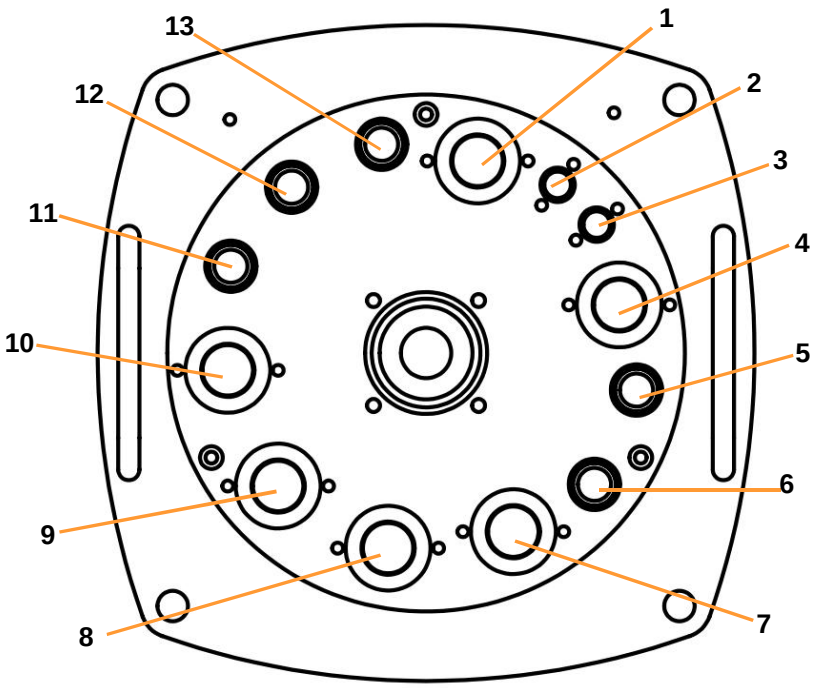
1	Ø 12 mm Pg13.5: pO_2 sensor	6	Ø 12 mm Pg13.5: Harvest pipe
2	Ø 12 mm Pg13.5: pH sensor	7	Ø 12 mm Pg13.5: Air pipe (sparger)
3	Ø 19 mm: 4 inlet push valve (reagent bottles fermentation / cultivation)	8	Ø 19 mm: Double inlet needle (acid / base CIP/SIP)
4	Ø 12 mm Pg13.5: Antifoam sensor	9	Ø 10 mm: Spare port
5	Ø 12 mm Pg13.5: Exit gas cooler	10	Ø 10 mm: Temperature sensor (Pt100)

4.5.2 Vessel Top Plate DN 150: Ports & Configuration



1 Ø 19 mm: Double inlet needle (acid / base CIP/SIP)
2 Ø 10 mm: Temperature sensor (Pt100)
3 Ø 10 mm: Spare port
4 Ø 19 mm: 4 inlet push valve (reagent bottles fermentation / cultivation)
5 Ø 12 mm Pg13.5: Air pipe (sparger)
6 Ø 12 mm Pg13.5: Harvest pipe
7 Ø 12 mm Pg13.5: Spare port
8 Ø 19 mm: Inoculation needle
9 Ø 12 mm Pg13.5: pO_2 sensor
10 Ø 12 mm Pg13.5: pH sensor
11 Ø 12 mm Pg13.5: Exit gas cooler

4.5.3 Vessel Top Plate DN 200: Ports & Configuration



1 Ø 19 mm: Harvest pipe

2 Ø 10 mm: Temperature sensor (Pt100)

3 Ø 10 mm: Spare port

4 Ø 19 mm: 4 inlet push valve (reagent bottles fermentation / cultivation)

5 Ø 12 mm Pg13.5: pO_2 sensor

6 Ø 12 mm Pg13.5: Spare port

7 Ø 19 mm: Spare port

8 Ø 19 mm: Spare port

9 Ø 19 mm: Inoculation needle

10 Ø 19 mm: Double inlet needle (acid / base CIP/SIP)

11 Ø 12 mm Pg13.5: Air pipe (sparger)

12 Ø 12 mm Pg13.5: pH sensor

13 Ø 12 mm Pg13.5: Exit gas cooler

5 Transport, Packaging and Storage

5.1 Safety Instructions for Transport

Personnel

Transport of the equipment may only be carried out by qualified personnel.

Inappropriate transportation

CAUTION!
Damage due to inappropriate transportation!

Inappropriate transportation may cause considerable loss of property.

Therefore:

– Handle packed items with care and caution when unloading on delivery, as well as during in-house transportation.
– Remove packaging finally only when the equipment is ready to be brought into use.

5.2 Transport Inspection

Immediately verify delivery on receipt for completeness and freedom from any transit damage.

Proceed as follows when transit damage is physically identifiable:

- Do not accept delivery or under reserve only.
- Note extent of loss on transport documentation or delivery note.
- Initiate complaint.

NOTICE!

Complain regarding a defect as soon as it is identified. Claims for damages can only be made within the effective terms for presenting complaints according to the manufacturer's general conditions of contract

5.3 Packaging

The packaging is composed exclusively of environmentally-friendly materials.

The equipment is packed in a wooden crate. Accessories are additionally packed in cardboard boxes.

The packaging is meant to protect the component parts against damage in transit or other events. Therefore, do not destroy the packaging and remove it only when the equipment is ready to be brought into use.

Handling of packaging materials

The packaging is the property of the purchaser on delivery. Hence the purchaser is obliged to dispose of it appropriately.

Dispose of packaging materials according to legal, statutory regulations and local directives.

CAUTION!
Environmental loss by incorrect disposal!

Packaging materials are valuable resources and can be reused, reprocessed or recycled in many cases.

Therefore:

– Packaging materials are to be disposed of in an environmentally suitable way.
– Adhere to local disposal directives. Engage a certified specialist if necessary.

Shipping conditions

Use only original packaging materials when re-dispatching the equipment or any components parts. Using the original packaging materials only make it possible to offer low-cost transportation.

5.4 Transport

WARNING!
Risk of injury due to inappropriate transportation.

Inappropriate transportation may lead to severe injuries and loss of property due to the equipment's weight and its bulky packaging material.

Therefore:

– Never transport the equipment alone
– Use a fork lift or a hand pallet truck for transportation
– Make all necessary safety arrangements to protect the equipment against falling off.

Transport of the wooden crate with a fork lift

The wooden crate can be moved by a fork lift in the following circumstances:

- The fork lift must be of appropriate design for the weight of the unit to be transported.
- The driver must be qualified for driving the fork lift.

To hook on:

1. Drive the fork lift with its forks between or under the crate's bars.
2. Move the forks so that they stand out on the opposite side.

   Ensure that the crate cannot tilt because of an eccentric balance point.
3. Lift the crate and start to transport it.

5.5 Storage

5.5.1 Storage of the Equipment in General

The equipment may only be stored under the following conditions:

- Do not store outdoors.
- Do not expose to aggressive media.
- Protect against solar radiation.
- Avoid mechanical abrasion damage.
- Check regularly on the general condition of all components and the packaging when storing for more than 3 months.
- Store the equipment and its components clean, dry and protected against dust, dirt or liquids of any kind.
- Storage temperature: 5 to 55 °C.
- Relative air humidity, non-condensing: 10 to 95 %.

5.5.2 Storage of the Reagent Bottles and Hoses

WARNING!
Risk of injury due to inappropriate storage of reagent bottles and hoses!

Residues of acid or base may damage the reagent hoses or elements of the bottle caps when storing unwashed reagent bottles and hoses. Damaged reagent hoses and elements of the bottle caps are a safety risk for the user when operating the equipment.

Therefore:

– Never store unwashed reagent hoses and bottles.

- Thoroughly rinse reagent bottles and hoses with distilled water before storing
- Store reagent bottles and hoses clean and dry

6 Installation

Faulty installation

WARNING!
Danger due to faulty installation!

Installation requires qualified and experienced personnel. Faulty installation may lead to perilous situations or severe loss of property

Therefore:

– Installation is to be carried out by the manufacturer's associates only.
– Call the manufacturer when any subsequent translocation is foreseen.
– Prevent arbitrary installation and translocation.

6.1 Safety

Personnel

- Installation may only be carried out by qualified personnel.
- Any work on the electrical system is strictly to be carried out by qualified electricians

Electrical system

DANGER!
Danger of fatal electric shock!

Contact with electrically powered components is perilous. Energised electrical components may perform uncontrolled movements which can lead to severe injuries.

Therefore:

– Turn off the electrical supply and check whether it is electrically isolated before starting any work.

6.2 Location Requirements for Installation

6.2.1 General Information

The following conditions must apply for the installation of the equipment:

- The equipment may only be installed inside buildings.
- Operating and room temperature: +5 to +40 °C
- Relative humidity, non-condensing: 20 – 90%
- Any other kind of set-up has to be checked/clarified with the manufacturer and needs their written authorisation.
- The supporting surface must be even and have adequate stability and carrying capacity.
- The supporting surface must have an appropriate working height (see chapter "Technical data").
- There must not be any sources of electrical interference in the environment.
- Ensure appropriate illumination at the workplace.

6.2.2 Minimum Spacing

To operate and maintain the equipment it must be installed with a minimum spacing of 100 mm from walls, ceilings or other equipment.

The front side of the equipment must always be accessible and the front door must be removable at any time.

The distance between the equipment and the bioreactor Labfors 5 is defined by the cable length of the vessel level sensor (LA600) and the different hose lines between both devices.

6.2.3 Compressed Air

WARNING!
Risk of explosion due to usage of dirty (contaminated) compressed air!

Using dirty compressed air carries a risk of explosion which may cause severe injuries and loss of property.

Therefore:

– Only use compressed air which is clean, dry and free from oil, grease and dust.

CAUTION!
Danger of loss of property due to use of oily or wet compressed air!

Use of oily or wet compressed air may lead to contamination in the system!

Therefore:

– Only use compressed air which is clean, dry and free of oil.

The supply of compressed air for the equipment must meet the following conditions:

Conditions compressed air

- Pressure connection 2 ± 0.5 bar
- Manometer for primary pressure control
- Constancy of air supply
- Use only compressed air which is dry, clean and free of oil, grease and dust
- Recommended pre-filter: 10 µm

Conditions hose

- Only use a pressure-resistant and intact hose
- Only use a hose with appropriate diameter, use an adaptor as necessary
- Secure the hose with an appropriate clamp

6.2.4 Exit Gas

- Ensure the exit gas is safely led away using the appropriate pressure-resistant and intact hose.
- Ensure the operating environment is provided with a ventilation system, appropriate to the application.

6.2.5 Water Inlet

The water supply for the equipment must meet the following conditions:

Conditions water supply

- Connection pressure 2 ± 1 bar
- Manometer for primary pressure control
- Water quality: demineralised, ≤ 1.5 mmol calcium carbonate / litre (soft)

NOTICE!

The water quality must comply with the quality accepted for the final rinsing (process phase Final Rinse). Therefore the water must have the quality of process water.

Conditions hose

- Only use a pressure-resistant and intact hose
- Only use a hose with appropriate diameter, use an adaptor as necessary
- Secure the hose with an appropriate clamp

6.2.6 Water Outlet

WARNING!
Health risk and danger to the environment due to contaminated water (condensate)!

Contaminated condensate water drains out during and after the CIP/SIP process. This presents a serious potential health risk for the user and danger to the environment if not drained off safely or when using inappropriate hoses.

Therefore:

– Only use heat resistant, pressure resistant, intact and appropriate hoses.
– Ensure the drain is heat resistant and has no backpressure
– Ensure, contaminated water is drained off safely and disposal is environmentally correct.
– Strictly adhere to safety regulations regarding biological safety.

The house drain line and the drain must meet the following conditions:

Conditions hose

- Only use a heat resistant, pressure-resistant and intact hose
- Only use a hose with appropriate diameter, use an adaptor as necessary
- Secure the hose with an appropriate clamp on the equipment side

Conditions drain

- Use a heat resistant drain which has no possibility of generating a back-pressure
- The drain must not be close-by the user.
- Waste water must be drained off safely and disposal must be environmentally correct.

6.2.7 Electric Power Supply

Personnel

Connection to be made by a qualified electrician only

Conditions

The electric power supply of the equipment must meet the following conditions:

- Single phase power supply
- 115 / 230 VAC
- 50/60 Hz
- Max. current consumption:
  - 115 VAC: 5 A
  - 230 VAC: 2.5 A
- The electrical power supply must be constant. Use a suitable filter and/or voltage stabilizer on the main power supply source, if this cannot be guaranteed.

7 Preparations for Use

7.1 Safety

Personnel

All preparatory work for use may only be carried out by qualified personnel in biology, biotechnology or chemical engineering.

WARNING!
Risk of injury due to inappropriate preparatory work!

Inappropriate preparatory work may lead to severe physical injury or loss of property.

Therefore:

– Carry out all preparatory work according to data in this operating manual.

7.2 Overview of Preparation for Use

If the equipment is correctly connected to in-house compressed air, water and power, some preparation work is required.

In the following chapters and sections all the preparation work required prior to the CIP/SIP process is described. Differentiation is made between:

- One-off work:
  this work only needs to be carried out once for normal operation.

NOTICE!

Some work has already been carried out in the factory on despatch of the equipment as a complete package with the Labfors 5 bioreactor.

- Recurring work:
  this work needs to be carried out before each CIP/SIP process.

7.2.1 One-Off Work Processes prior to the CIP/SIP Process

The following work is generally carried out once:

- Mount and correctly position the third impeller on the stirrer shaft of the Labfors 5 bioreactor
- Insert and correctly position the harvest pipe in the vessel top plate and vessel of the Labfors 5 bioreactor
- Install the air pipe (sparger) in the vessel top plate and vessel of the Labfors 5 bioreactor
- Mount and correctly position the level sensor on the vessel of the Labfors 5 bioreactor
- Check the sensitivity of the vessel level sensor (LA600), adjust it as necessary

NOTICE!

The work specified above is already carried out in the factory. However, the following chapters will also describe how to perform this work along with the work specified below which is to be carried out by the user.

- Connect the level sensor to the equipment (*Level Sensor Bioreactor LA600*)
- Connect the air pipe (sparger) to the equipment (hose tree: *LabCIP to sparger*)
- Install the exit gas cooler in the vessel top plate of the Labfors 5 bioreactor and connect to the water supply on the basic unit of the bioreactor
- Connect the exit gas cooler to the equipment (hose tree: *LabCIP to Air cooler*)
- Connect the control cable from the basic unit of the Labfors 5 bioreactor to the equipment (*control*)
- **Option Water leak detector:** if present, place the detector into the drip tray
- Fill the temperature control circuit (vessel jacket) of the Labfors 5 bioreactor with water

7.2.2 Recurrent Work Processes prior to the CIP/SIP Process

The following work is to be performed before every CIP/SIP process:

- Calibrate the pH sensor to pH 12 and pH 7
- Sterilise the closed semi-automatic push valve with exit gas filter in the autoclave
- Sterilise the closed semi-automatic push valve with inlet air filter in the autoclave
- Sterilise the closed 4 inlet push valve with connected reagent bottles and pump heads for fermentation / cultivation after the CIP/SIP process in the autoclave

  Integrate the bottle for medium via a Y-piece (not supplied) in the feed line so that once the CIP/SIP process has been completed the medium can be aseptically pumped via the feed pump into the culture vessel.
- Sterilise the Super Safe Sampler sampling system with closed three-way cock for fermentation / cultivation after the CIP/SIP process in the autoclave

After sterilisation in the autoclave

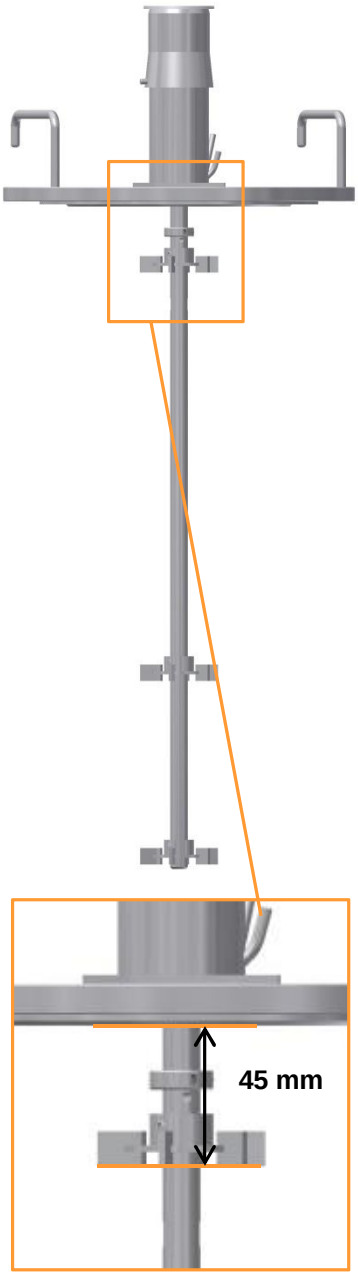
- Connect the Super Safe Sampler sampling system with closed three-way cock and hose piece to the harvest pipe and to the equipment (hose tree: *LabCIP to harvest pipe*)

NOTICE!

The Super Safe Sampler sampling system MUST be integrated with the three-way cock in the hose line between the harvest pipe and the equipment.

- Screw in the closed semi-automatic push valve with exit gas filter to the exit gas cooler and connect to the equipment (connection: *to air cooler*)
- Screw in the closed semi-automatic push valve with inlet air filter to the air pipe (sparger) and connect to the basic unit of the Labfors 5 bioreactor
- Install the closed 4 inlet push valve with connected reagent bottles and medium bottle (integrated via a Y-piece in the feed line) and pump heads in the vessel top plate port
- Connect the reagent bottles with acid and base for the CIP/SIP process with double inlet needle and pump heads
- Fit the pump heads onto the drive shafts to the basic unit of the Labfors 5 bioreactor

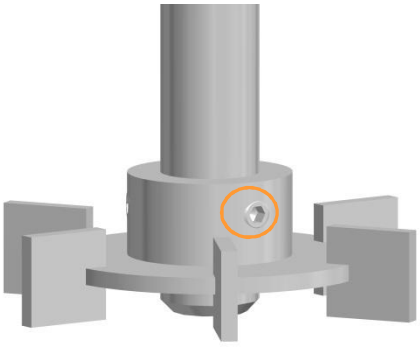
7.3 Checking the Position of the Impellers



The number and positioning of the impellers (Rushton type) on the stirrer shaft of the bioreactor contribute significantly to the success of the CIP/SIP process.

When the equipment is delivered together with the Labfors 5 bioreactor, all three impellers are installed and correctly positioned.

- Top impeller: is positioned in such a way that there is 45 mm between the lower edge of the vessel top plate and the lower edge of the impeller blade
- Middle impeller: is positioned about one third (measured from the bottom) of the distance from the stirrer shaft
- Bottom impeller: is positioned right at the end of the stirrer shaft

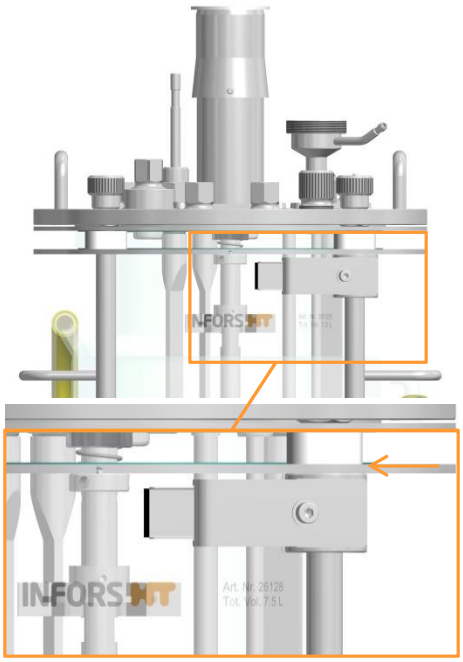


The impellers are fixed to the stirrer shaft using grub screws (2 pieces). To reposition an impeller, you only need to loosen the grub screws a little. The correct Allen key is supplied with the Labfors 5 bioreactor.

NOTICE!

Detailed descriptions on the handling of the culture vessel and its components are in the operating manual of the Labfors 5 bioreactor and are not repeated in detail in this operating manual.

7.4 Checking the Position of the Vessel Level Sensor



When the equipment is delivered together with the Labfors 5 bioreactor, the vessel level sensor is already installed and correctly positioned in a holder.

The level sensor must be in such a position that the top edge of the sensor holder is in contact with the lower ring of the vessel holder. This ensures that the vessel is filled with fluid to the highest possible level in the various filling sequences during the CIP/SIP process. It also ensures that the topmost impeller rotates in liquid and therefore the best possible cleaning efficiency can be achieved.

NOTICE!

For details on the positioning of the stirrer see the section “Checking the Position of the Impellers”.

So that the level sensor is fully functional, it needs to rest firmly on the glass surface of the vessel. It is also important that there are no vessel components are covering the sensor.

NOTICE!

For details on the vessel top plate configuration see the section “Vessel Top Plate Configuration” in the main chapter “Setup and Function”.

7.4.1 Changing the Position of the Vessel Level Sensor

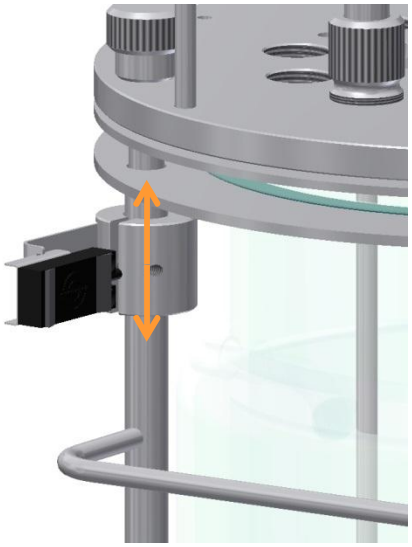
To change the position of the level sensor, proceed as follows:

Procedure

1. Loosen the Allen screw on the retaining bracket – do not remove.

2. Take the retaining bracket off of the vessel.

The holder can now be moved up or down at the base of the vessel holder.



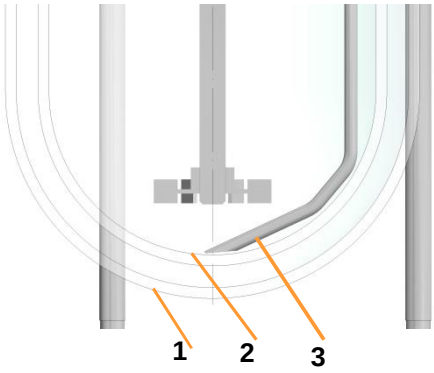
3. Press the level sensor with the retaining bracket on to the vessel wall and tighten the Allen screw.

7.5 Checking the Installation Height of the Harvest Pipe

When the equipment is delivered together with the Labfors 5 bioreactor, the harvest pipe is already installed on the vessel top plate using a clamping adaptor and the installation height is correct.

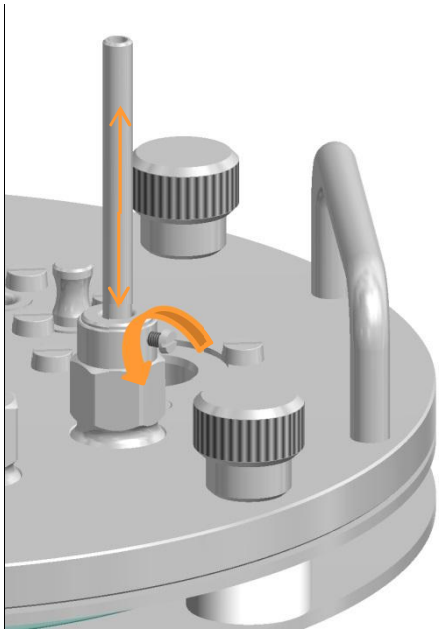
NOTICE!

For details on the vessel top plate configuration see the chapter "Vessel Top Plate Configuration" in the main chapter "Setup and Function".



To guarantee complete vessel emptying during the various emptying sequences in the CIP/SIP process, the tip of the harvest pipe must be positioned at the lowest point of the vessel.

1 Vessel jacket
2 Vessel base
3 Harvest pipe



After loosening the slotted cylinder head screw on the clamping adaptor you can adjust the height of the harvest pipe. Tightening the slotted cylinder head screw fixes the harvest pipe in place in the clamping adaptor.

For installation/dismantling the harvest pipe is inserted from below in the vessel top plate port and in the clamping adaptor or pulled out from below.

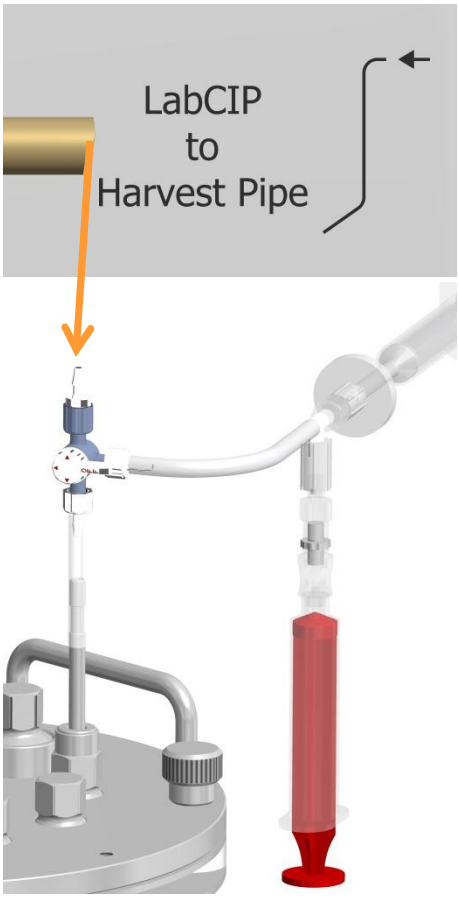
NOTICE!

Detailed descriptions on the handling of the culture vessel and its components are in the operating manual of the Labfors 5 bioreactor and are not repeated in detail in this operating manual.

7.6 Connecting the Harvest Pipe

To connect the harvest pipe to the equipment, proceed as follows:

Procedure



1. Attach the hose of the equipment connection *LabCIP to Harvest pipe* to the free Luer connector on the three-way cock of the Super Safe Sampler sampling system.

NOTICE!

The three-way cock with Super Safe Sampler MUST be integrated in the hose line! Otherwise it is not possible to perform sampling during subsequent fermentation / cultivation. For details see chapter "Preparing the Super Safe Sampler Sampling System with Three-Way Cock".

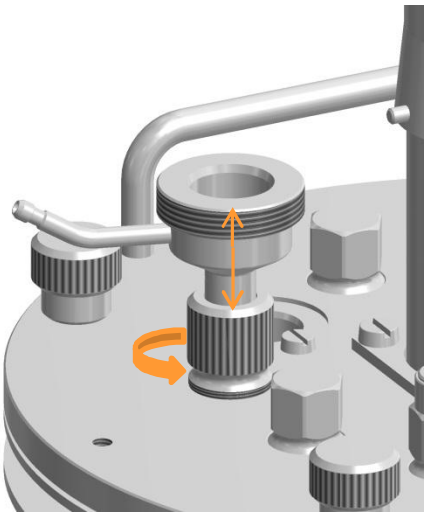
2. Secure the hose with a cable tie.

7.7 Installing the Air Pipe (Sparger)

When the equipment is delivered together with the Labfors 5 bioreactor, the air pipe (sparger) is already installed on the vessel top plate. The installation height is determined by the stop on the fitting adapter.

NOTE!

For details on the air pipe, see the chapter "Air Pipe (Sparger) with Semi-Automatic Push Valve" in the main chapter "Setup and Function". For details on the vessel top plate configuration see the chapter "Vessel Top Plate Configuration" in the main chapter "Setup and Function".

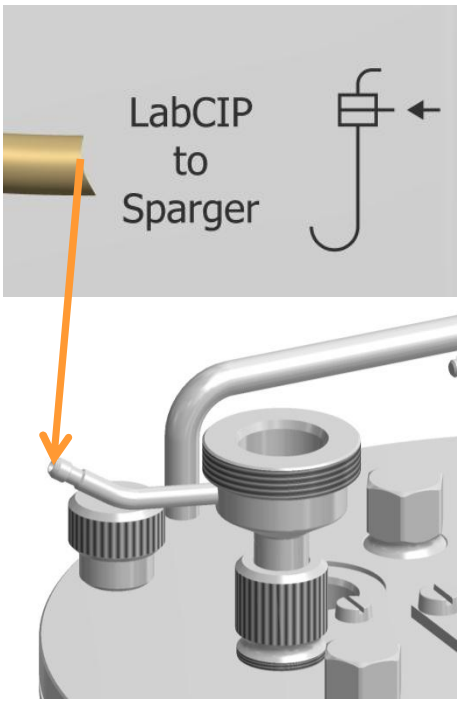


For installation/dismantling, the hollow screw on the fitting adapter needs to be loosened. Then the air pipe (sparger) can be inserted in the vessel top plate port or removed from above.

7.8 Connecting the Air Pipe (Sparger)

To connect the air pipe (sparger) to the equipment, proceed as follows:

Procedure



1. Attach the hose of the equipment port *LabCIP to sparger* to the lateral hose nozzle on the connection thread of the air pipe (sparger).

2. Secure the hose with a cable tie.

7.9 Mounting the Exit Gas Cooler

The exit gas cooler can be simply screwed into the vessel top plate. Before screwing in, ensure that there is an O-ring in the vessel top plate, insert one if necessary.

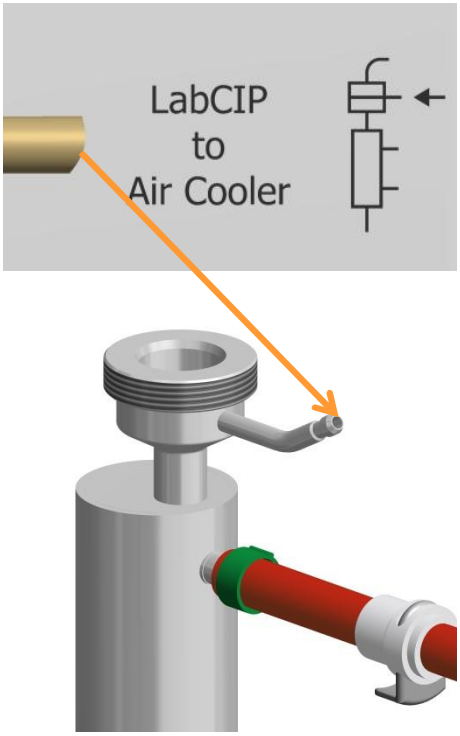
NOTICE!

For details on the vessel top plate configuration see the chapter “Vessel Top Plate Configuration” in the main chapter “Setup and Function”.

7.10 Connecting the Exit Gas Cooler to the Equipment

To connect the exit gas cooler to the equipment, proceed as follows:

Procedure



1. Attach the hose of the equipment port *LabCIP to air cooler* to the lateral hose nozzle on the connection thread of the exit gas cooler.

2. Secure the hose with a cable tie.

NOTICE!

The water supply for the exit gas cooler is supplied as standard via the basic unit of the Labfors 5 bioreactor. Follow the instructions in the Labfors 5 operating manual.

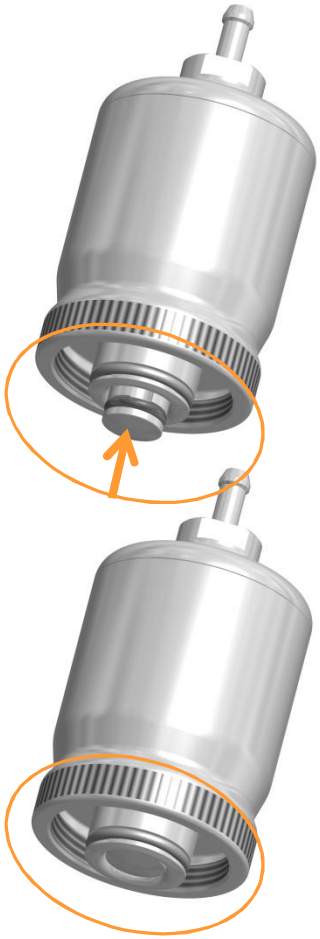
7.11 Preparing the Air Pipe and Exit Gas Cooler Push Valves

The two semi-automatic push valves for the exit gas cooler and the air pipe (sparger) need to be sterilised separately in the autoclave before the CIP/SIP process. Only then can they be installed and connected.

7.11.1 Autoclaving

Before sterilising in the autoclave ensure, if necessary carry out:

Procedure



1. Manually close both push valves:
   to do this press the valve inwards (A) until it audibly and visibly clicks in place (B) inside.

2. Attach a piece of hose for inlet air (starter kit) to the hose nozzle on the push valve.

3. Attach the inlet air filter (starter kit) to the hose.

   The red marking on the disposable filter is on the filter side facing away from the push valve.

4. Ensure that the push valve for the exit gas cooler is correctly equipped with hose and exit gas filter, equip if necessary.

   The green marking on the disposable filter is on the filter side facing the push valve.

5. Wrap up both push valves in aluminium foil.
6. Lightly cover the exit gas filter and inlet air filter with aluminium foil.
7. Sterilise everything together in the autoclave.

7.11.2 Mounting and Connection

After sterilisation in the autoclave and sufficient cooling down time, proceed as follows:

Procedure

1. Remove the aluminium foil from the push valves and filters.

Push valve exit gas cooler:

2. Screw the push valve onto the connection thread on the exit gas cooler.

3. Attach the hose (Ø = 4 x 7 mm) of the equipment connection *to air cooler* to the push valve of the exit gas cooler.

NOTICE!

The hose (illustrated in the left figure as an orange line) is pre-installed on delivery of the equipment. A spare hose is included in the starter kit.

Preparations for Use

Push valve air pipe (sparger)

4. Screw the push valve onto the connection thread on the air pipe (sparger).

5. Attach the piece of silicone hose for inlet air (Ø = 5 x 8 mm / starter kit) to the hose nozzle for inlet air on the basic unit of the bioreactor.

6. Secure the pressure hose with a cable tie.

7. Attach the open end of the hose to the inlet air filter on the push valve of the air pipe (sparger).

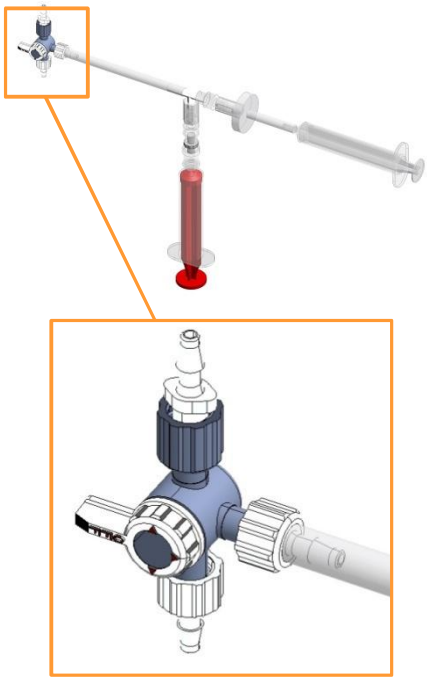
7.12 Preparing the Super Safe Sampler Sampling System with Three-Way Cock

The Super Safe Sampler sampling system, which is used for the subsequent fermentation / cultivation, must be sterilised separately in the autoclave with closed three-way cock, before the CIP/SIP process, and then connected to the harvest pipe.

7.12.1 Autoclaving

Proceed as follows for sterilising in the autoclave:

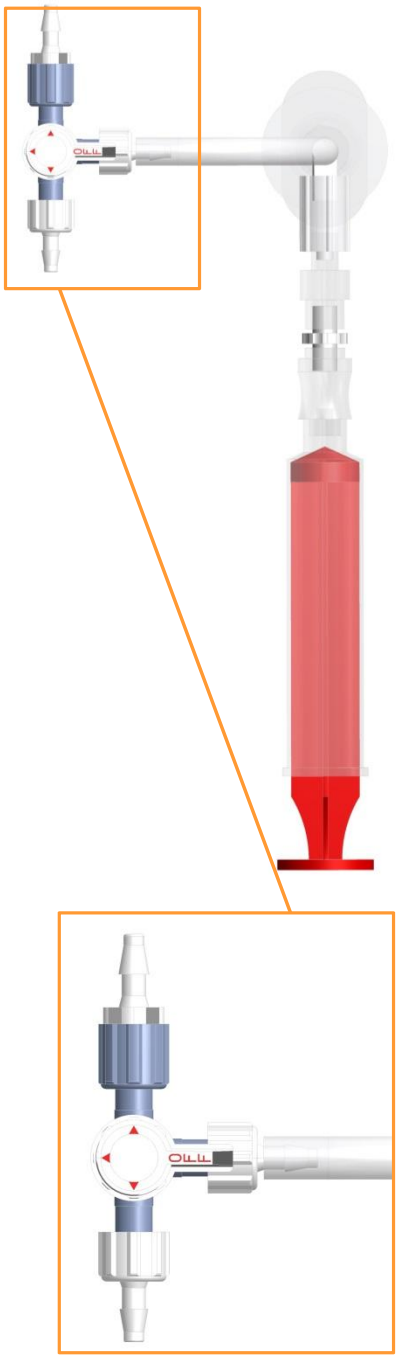
Procedure



1. Fit the three-way cock to the hose piece on the Super Safe Sampler.

NOTICE!

Ensure that the hose line of the Super Safe Sampler is still closed (OFF) to guarantee the sterility of the sampling system.



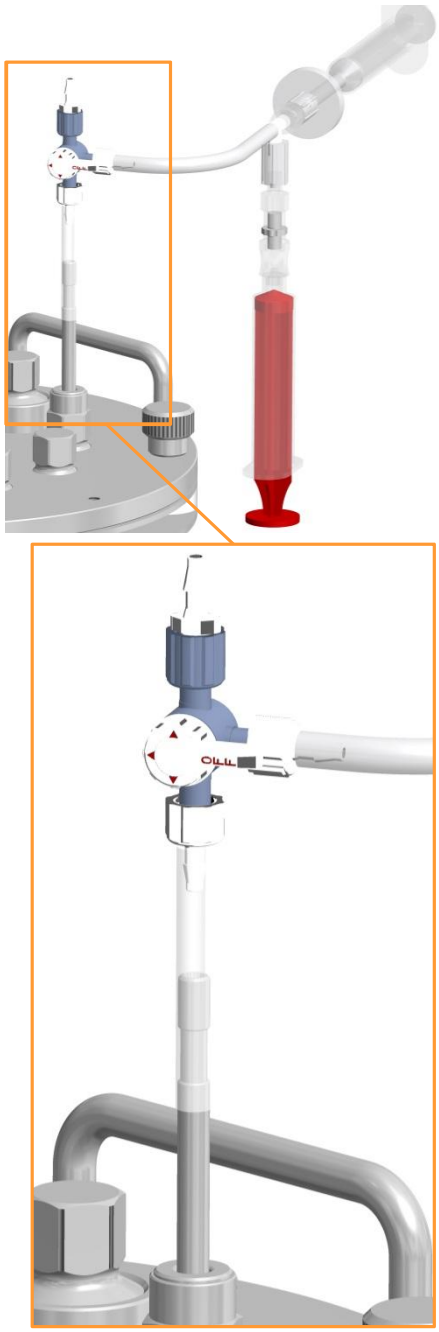
2. Turn the cock so that the hose line of the Super Safe Sampler is closed (OFF).

3. Loosely cover the valve assembly including filter and three-way cock on the Super Safe Sampler with aluminium foil.
4. Sterilise the Super Safe Sampler in the autoclave.

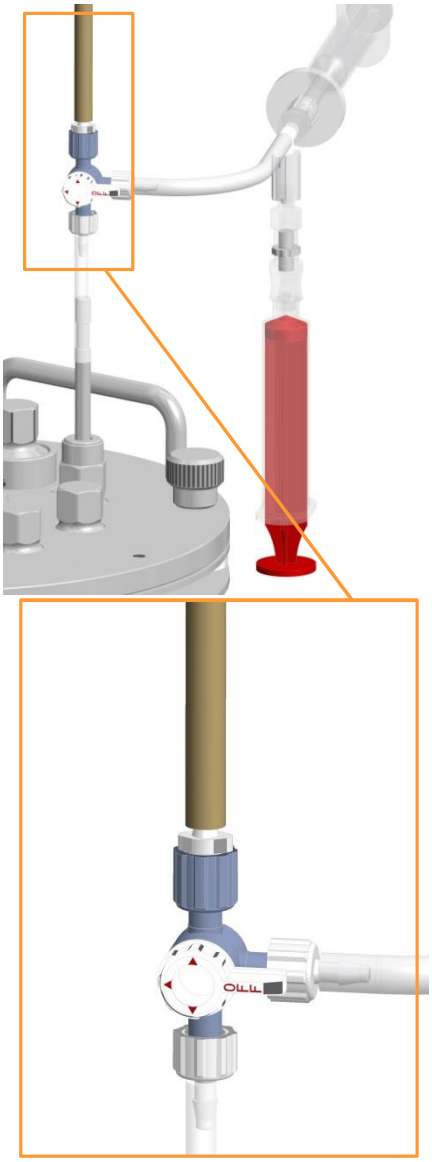
7.12.2 Connection

After sterilisation in the autoclave and sufficient cooling down time, proceed as follows:

Procedure



1. Fit the short silicone hose piece (supplied with the three-way cock) to the harvest pipe.
2. Fit the three-way cock on the Super Safe Sampler to the hose piece.



3. Attach the hose of the equipment connection *LabCIP to Harvest pipe* to the free Luer connector on the three-way cock.

NOTICE!
See also the section "Connecting the harvest pipe".

4. Secure the hose with a cable tie.

7.13 Preparing the 4 Inlet Push Valve with Reagent Bottles and Pump Heads

The manual 4 inlet push valve, along with the reagent bottles and pump heads for subsequent cultivation / fermentation, needs to be sterilised separately in the autoclave prior to the CIP/SIP process. Only then can the 4 inlet push valve be mounted to the vessel top plate.

So that the medium can be pumped aseptically via the feed pump in the culture vessel once the CIP/SIP process has been completed, the bottle for the medium needs to be integrated by means of a Y-piece (not supplied) in the feed line.

By opening / closing in accordance with fitted hose clamps (not supplied), you can later select whether the feed pump should pump from the bottle with medium or from the bottle with feed medium.

7.13.1 Autoclaving

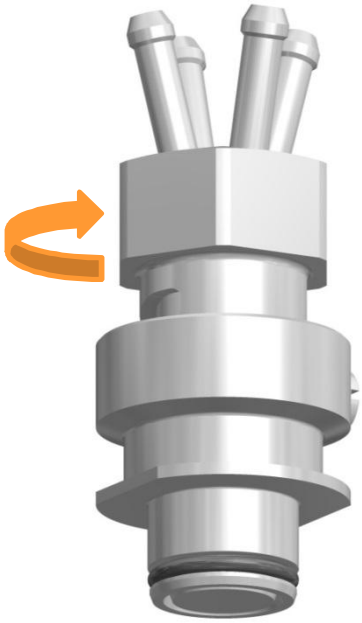
Proceed as follows for sterilising in the autoclave:

Procedure

1. Ensure that the 4 inlet push valve is equipped with an intact O-ring, otherwise fit one.
2. Fill and label reagent bottles as normal, and connect to the Labfors 5 bioreactor with relevant pumps.

> *NOTICE!*
>
> *The preparatory work of the reagent bottles and pumps for the fermentation / cultivation are described in detail in the operating manual of the Labfors 5 bioreactor and are not repeated here.*

3. Fit the hose ends of the reagent bottles to the hose nozzles on the 4 inlet push valve and secure with cable ties.
4. Integrate the bottle for the medium in the feed line using a Y-piece (not supplied).
5. Close the 4 inlet push valve:
   turn the rotary piston anticlockwise.



6. Pull the mounting plate with the pump heads off the drive shafts on the basic unit of the bioreactor.

7. Cover the filter (for pressure equalisation during sterilisation) on the reagent bottles lightly with aluminium foil.
8. Clamp off the hoses near to the reagent bottles connections.
9. Cover the 4 inlet push valve lightly with aluminium foil.
10. Place the reagent bottles in the reagent bottle and pump holder of the bioreactor, attach the mounting plate to the pump heads.
11. Sterilise the bottle for the medium, reagent bottles with pump heads and the 4 inlet push valve in the autoclave.

7.13.2 Mounting

After sterilisation in the autoclave and sufficient cooling down time, proceed as follows:

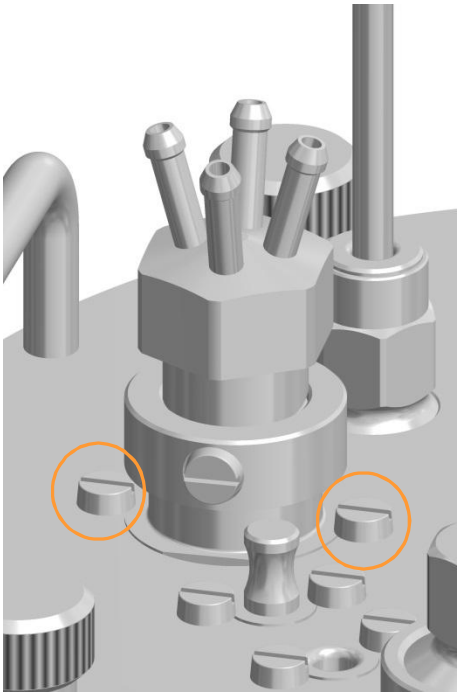
Procedure

1. Mount the reagent bottle and pump holder on the vessel.
2. Remove the aluminium foil from the 4 inlet push valve and filters on the reagent bottles.
3. Loosen the cylinder head screws next to the 19 mm vessel top plate port.

NOTICE!

For details on the vessel top plate configuration see the chapter “Vessel Top Plate Configuration” in the main chapter “Setup and Function”.

4. Insert the 4 inlet push valve in the vessel top plate port.



5. Tighten the cylinder head screws.

> *NOTICE!*
>
> *The left figure provides a general understanding. It shows the mounted manual 4 inlet push valve without any reagent bottle attached.*

7.14 Preparing the Acid/Base Reagent Bottles

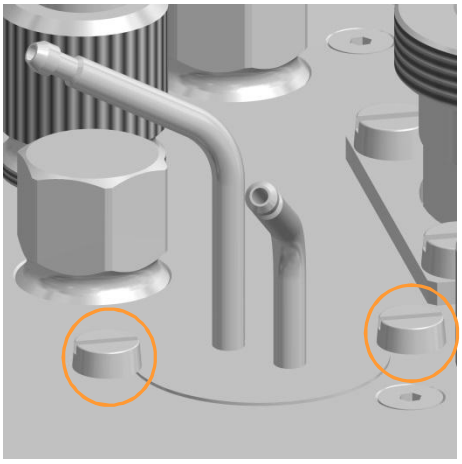
The reagent bottles with acid and base for the CIP/SIP process are prepared as follows:

Procedure

1. Ensure that the double inlet needle is equipped with an intact O-ring, otherwise fit one.
2. Loosen the cylinder head screws next to the 19 mm vessel top plate port.

> *NOTICE!*
>
> *For details on the vessel top plate configuration see the chapter “Vessel Top Plate Configuration” in the main chapter “Setup and Function”.*

3. Insert the double inlet needle in the vessel top plate port.



4. Tighten the cylinder head screws.

5. Fill and label the reagent bottles with acid and base.

NOTICE!

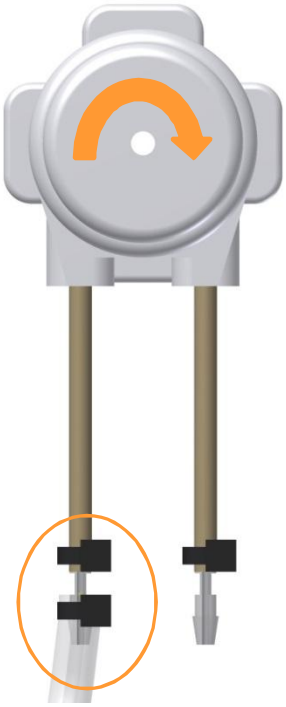
For details on the permitted acids and bases see the table in section "Utitlities" in the main chapter "Technical data".

6. Fit the reagent bottles with long hoses (silicone hoses are supplied with reagent bottles).

The length of the hoses must be such that there are no kinks or tension in the lines between the reagent bottles and pumps (in operating mode).

7. Secure the hoses with cable ties.

Preparations for Use

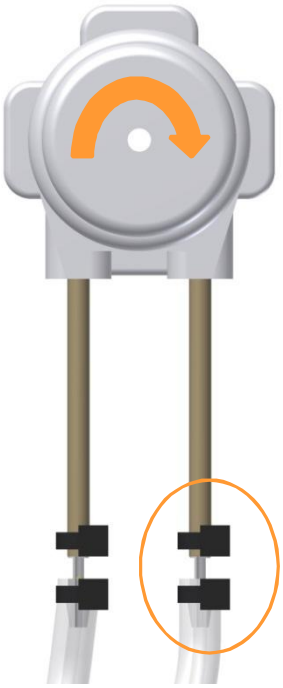


8. Connect the hoses of the reagent bottles using hose connectors (included in the bioreactor starter kit) to the left pump hoses and secure with cable ties.

   In doing so, note the direction of rotation of the pumps (clockwise).

9. Cut two more lengths of hose.

   The length of the hoses must be such that there are no kinks or tension in the lines between the reagent bottles and the double inlet needle in the vessel in operating mode.



10. Connect the hoses using hose connectors (included in the bioreactor starter kit) to the right pump hoses and secure with cable ties.

11. Attach the hoses to hose nozzles on the double inlet needle.
12. Secure the hoses with cable ties.

13. Place the reagent bottles in the bottle holder.
14. Attach the mounting plate with pump heads to the drive shafts of the acid pump *acid* and base pump *base* on the basic unit of the bioreactor.
15. Push the pump cover plate into the holder.

7.15 Calibrating the pH Sensor

A 2-point calibration using pH 7 and pH 12 buffer solutions of the pH sensor (type “ARC”, manufacturer HAMILTON) must be performed prior to every CIP/SIP process.

NOTICE!

The calibration and installation of the pH sensor are described in detail in the operating manual of the Labfors 5 bioreactor and are not repeated in this operating manual.

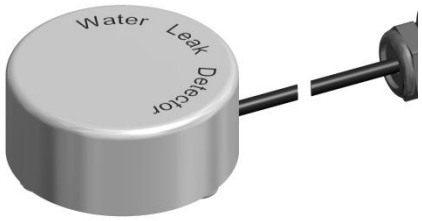
7.16 Connecting the Vessel Level Sensor

To connect the vessel level sensor to the equipment, simply insert the connector of the sensor cable on the equipment (*Level Sensor Bioreactor LA600*) into the connector on the cable of the level sensor and screw in.

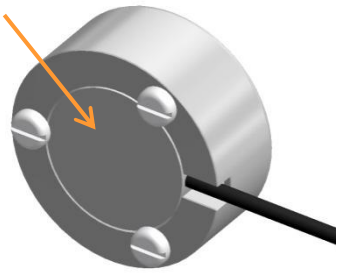
7.17 Connecting the Control Cable

To connect the bioreactor control cable to the equipment simply insert the connector of the control cable of the bioreactor basic unit into the 5-pin connector socket (*control*) on the equipment and tighten.

7.18 Option Water Leak Detector: Placing the Detector



If the optional water leak detector (LA602) is present, it must be placed in the drip tray before starting the process.



NOTICE!

Check if the contact surface of the water leak detector is clean. Wipe it with a damp cloth as necessary.

7.19 Checklist CIP/SIP Process

Equipment	■ Equipment is correctly connected to the power, compressed air and water supply
Impellers	■ The third impeller is installed on the stirrer shaft ■ All three impellers are correctly positioned on the stirrer shaft
Harvest pipe	■ The installation height of the harvest pipe is correct ■ The harvest pipe is connected to the hose tree of the equipment, the hose is secured with a cable tie
Super Safe Sampler sampling system and three-way cock	■ The Super Safe Sampler sampling system is autoclaved together with the three-way cock and integrated in the hose line of the harvest pipe. ■ Three-way cock is closed in the Super Safe Sampler direction
Vessel level sensor (LA600)	■ The vessel level sensor (LA600) is correctly positioned and connected to the equipment ■ The sensor's sensitivity is checked and adjusted as necessary
Air pipe (sparger)	■ The air pipe is connected to the hose tree of the equipment; the hose is secured with a cable tie.
Exit gas cooler	■ The exit gas cooler is connected to the hose tree of the equipment, the hose is secured with a cable tie ■ The exit gas cooler is connected to the water supply of the bioreactor basic unit, for details see the Labfors 5 operating manual
Push valves (semi-automatic)	■ Push valves are closed, autoclaved and screwed in to the connection thread of the exit gas cooler and air pipe (sparger) ■ The push valve on the exit gas cooler is connected to the equipment ■ The push valve on the air pipe is connected to the inlet air of the bioreactor basic unit

Preparations for Use

4 inlet push valve (manual) and reagent bottles	■ The 4 inlet push valve is closed and autoclaved together with the reagent bottles and pump heads for subsequent fermentation / cultivation and connected to the vessel
Bottle for medium	■ The bottle for the medium is integrated in the feed line via a Y-piece.
Double inlet needle with acid and base bottle	■ The acid/base reagent bottles are connected to the double inlet needle in the vessel top plate and to the pumps, the pumps are attached to drive shafts
Control cable	■ The control cable of the bioreactor basic unit is connected to the equipment
Sensors	■ The pH sensor is calibrated, installed and connected, see Labfors 5 operating manual ■ The temperature sensor is inserted in the pocket in the vessel top plate, see Labfors 5 operating manual ■ All sensors required for subsequent fermentation / cultivation are installed
Bioreactor basic unit	■ The bioreactor basic unit is correctly connected to the power, process air/gas and water supply and ready for use see Labfors 5 operating manual.
Motor / drive	■ The mechanical seal of the stirrer shaft has been lubricated, see Labfors 5 operating manual ■ The motor is coupled, cable is connected, see Labfors 5 operating manual

Preparations for Use

Bioreactor vessel

- The vessel jacket is connected to the water supplies of the bioreactor basic unit and filled, see the Labfors 5 operating manual
- All unused vessel ports are sealed, see Labfors 5 operating manual

NOTICE!

If the type of antifoam sensor is in use, which is dosing needle at the same time: the needle is closed with a piece of hose which is clamped off. The hose line for addition of antifoam agent is connected to one of the inlets of the 4 inlet push valve instead.

CIP/SIP process configuration

- The CIP/SIP process has been configured in the configuration menu. See the chapter “Configuration Menu” and the various subchapters in the main chapter “Operation”.

OPTION: Water leak detector

- The water leak detector (LA602) is placed in the drip tray.

8 Operation

8.1 Safety

Personnel

The equipment may only be operated by qualified personnel in biology, biotechnology or chemical engineering.

Inappropriate operation

WARNING!
Risk of injury due to inappropriate operation!

Inappropriate operation may lead to severe physical injury or loss of property.

Therefore:

– Strictly follow the instructions stated in this operating manual.

8.2 CIP/SIP Process – Brief Description of Process Run

The CIP/SIP process runs fully automatically which means that no manual interventions are required throughout the entire process.

The CIP/SIP process consists of four process phases:

- Process phase 1: Cleaning with base
- Process phase 2: Cleaning with acid
- Process phase 3: Sterilisation
- Process phase 4: Final rinsing with water

Within the entire CIP/SIP process, phases 1 to 3 are optional. This means that they can be activated or deactivated before the start of the process. In comparison, process phase 4 cannot be deactivated.

The following sections will briefly describe the process phases.

8.2.1 Process Phase 1 – Cleaning with Base

Process phase 1 (optional) essentially runs as follows:

Filling the vessel with water

The vessel is filled with water alternately via the exit gas and inlet air line up to the level sensor (**LA600**).

Cleaning with base

Base is added via the *base* pump at a factory pre-determined temperature until the configured pH value is reached.
The stirrer starts and stirs at a configured speed. The system heats up to the configured temperature. Cleaning continues until the configured time has elapsed.

Neutralisation with acid (optional)

Acid is added via the *acid* pump until the configured pH value is reached.

Emptying

The vessel is emptied once the configured time has elapsed.

Rinsing with water (optional)

The vessel is filled with water alternately via the exit gas and inlet air line up to the level sensor (**LA600**) and rinsed with water at a configured temperature until the configured time has elapsed. The vessel is emptied once the configured time has elapsed. The number of rinse cycles can be configured.

8.2.2 Process Phase 2 – Cleaning with Acid

Process phase 2 (optional) essentially runs as follows:

Filling the vessel with water

The vessel is filled with water alternately via the exit gas and inlet air line up to the vessel level sensor (**LA600**).

Cleaning with acid

Acid is added via the *acid* pump at a factory pre-determined temperature until the configured pH value is reached.
The stirrer starts and stirs at a configured speed. The system heats up to the configured temperature. Cleaning continues until the configured time has elapsed.

Neutralisation with base (optional)

Base is added via the *base* pump until the configured pH value is reached.

Emptying

The vessel is emptied once the configured time has elapsed.

Rinsing with water (optional)

The vessel is filled with water alternately via the exit gas and inlet air line up to the level sensor (**LA600**) and rinsed with water at a configured temperature until the configured time has elapsed. The vessel is emptied once the configured time has elapsed. The number of rinse cycles can be configured.

8.2.3 Process Phase 3 – Sterilisation

Process phase 3 (optional) essentially runs as follows:

Filling the vessel and circuit

The vessel and the complete circuit are filled with water alternately via the exit gas and inlet air line up to the circuit level sensor (**LA601**).

Sterilising with base

The circulation pump is activated. Base is added via the *base* pump at a factory pre-determined temperature until the configured pH value is reached.
The stirrer starts and stirs at maximum speed.
The system heats up to the configured temperature. Sterilisation continues until the configured time has elapsed.

Neutralisation with acid (optional)

Acid is added via the *acid* pump until the configured pH setpoint is reached.

8.2.4 Process Phase 4 – Final Rinsing with Water

Process phase 4 essentially runs as follows:

Emptying / opening the exit gas cooler push valve (612)

The exit gas line is rinsed with water.
The vessel is emptied; the push valve (**612**) in the exit gas line is opened by compressed air. This enables sterile air to flow into the vessel via the exit gas filter. The resulting excess pressure in the culture vessel pushes out the liquid from the vessel through the harvest pipe.

Rinsing the vessel with water and emptying

The vessel is filled with water via the exit gas and inlet air line up to the vessel level sensor (**LA600**).

The stirrer starts and stirs at a configured speed. The vessel is rinsed with water until the configured time has elapsed.
The vessel is emptied once the time has elapsed. The number of rinse cycles can be configured.

Last emptying / opening the air pipe push valve (613)

After the last emptying, the push valve (**613**) in the inlet air line is opened by compressed air. This enables sterile air to flow into the vessel via the inlet air filter.

8.2.5 Guide Values for Duration of Vessel Filling

The fill duration of the vessel, as with the duration of emptying, is dependent on the vessel size and factors such as primary pressure, viscosity, hoses etc. The following table therefore only contains guide values.

Vessel size	Approximate fill duration
2 litres	6 minutes
3.6 litres	11 minutes
7.5 litres	22 minutes
13 litres	38 minutes

8.3 CIP/SIP Process – Control

The CIP/SIP process is controlled using the touch screen operating panel of the Labfors 5 bioreactor.

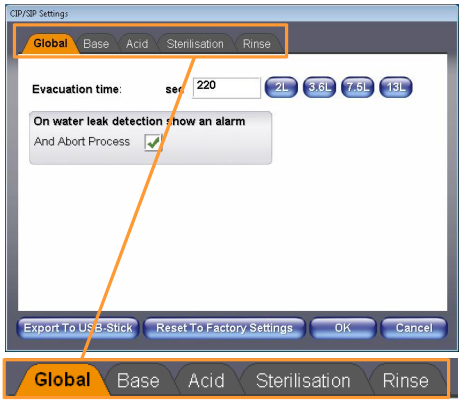
NOTICE!

A detailed description of the touch screen operating and control panel of the Labfors 5 bioreactor can be found in the bioreactor operating manual.

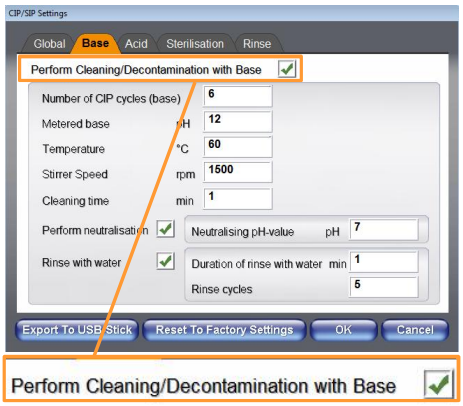
The configuration menu can be called up via the main menu *System* in the sub menu *Settings* using the **CIP/SIP settings** button.

NOTICE!

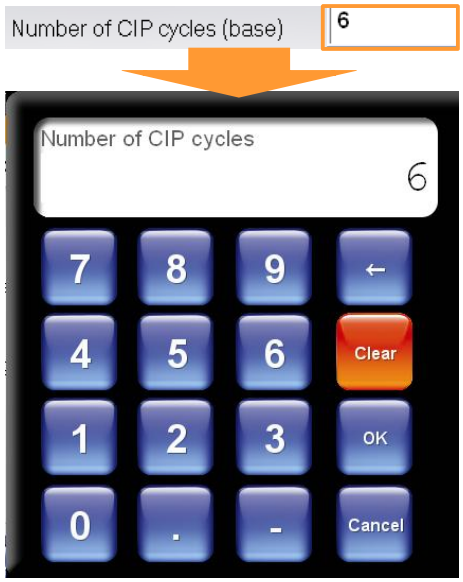
The configuration menu can only be accessed from the administrator user level.



All process conditions are set out in the five sub menus of the configuration menu *LabCIP configuration* . The submenus can be accessed via the five tab pages in the header of the configuration menu.

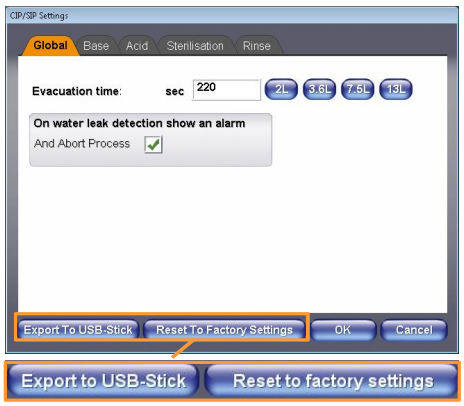


Optional functions are activated (switched on) or deactivated (switched off) by touching the check box. In the example in the left figure, the function *Perform cleaning / decontamination with base* is switched on..



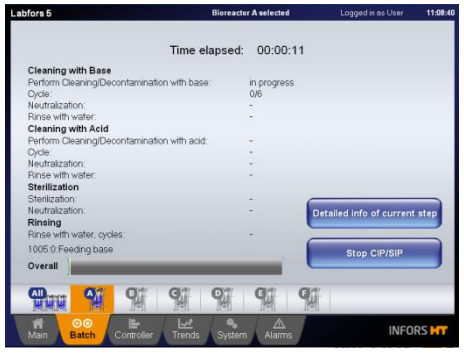
Values are typed in using a numeric keypad. This appears after touching any input field.
In the example in the left figure the numeric keypad is shown for entering the number of cleaning cycles with base (tap on input field *Number of CIP cycles base*).

Operation

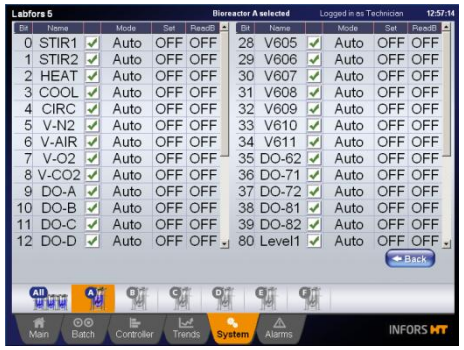


Buttons with functions for saving set values on a USB stick and restoring values to factory settings are also available in the configuration menu.

The process is started in the main menu *Batch* using the **Perform CIP/SIP** button**.**



During the ongoing CIP/SIP process, the process development is displayed on the screen.

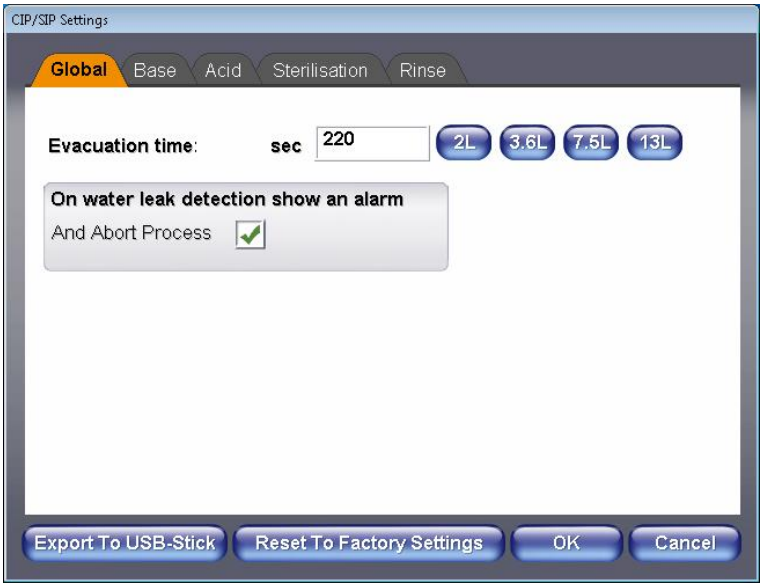


Valve settings, pumps, relay, digital inputs and outputs can be viewed in the sub menu *VALVES* under the main menu *System*.

Operation

The following chapters describe both the configuration menu with its functions and submenus and starting the process, overview of process development and cancelling the process in detail.

8.4 Configuration Menu - Overview



Header

The configuration menu contains five submenus shown as tabs in the header. The following settings are made in these five submenus:

- *Global*: to set the duration of the vessel emptying in seconds. The setting applies to all four process phases.
  If present: configuring the operating method of the optional water leak detector.
- *Base*: settings for base rinsing
- *Acid*: settings for acid rinsing
- *Sterilisation*: settings for sterilisation
- *Rinse*: settings for final rinsing

Touching the appropriate tab opens the selected submenu.

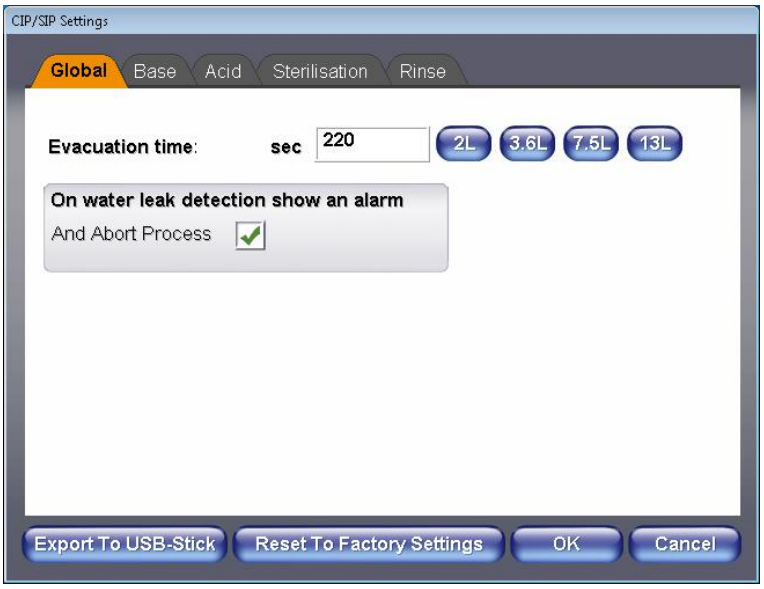
Footer

Four buttons with the following functions are provided in the footer of the configuration menu:

- **Export to USB-Stick**: to store the settings on a USB stick

- **Reset to factory settings**: to reset all values to factory settings
- **OK**: to save settings and close the configuration menu
- **Cancel**: to close the configuration menu without changes

8.4.1 Submenu Global – Emptying Duration of Vessel



The submenu *Global* only contains the input field *Evacuation time: sec.* This is where you can set the duration of vessel emptying in seconds.

The value set here applies to all four process phases.

The duration of emptying must be sufficiently long as the system does not have a function to detect the fill quantity in the vessel. The size of the vessel to be cleaned must be taken into account when setting the time. This means that the larger the vessel, the longer its emptying. Similarly, factors such as primary pressure, viscosity of the liquid, hoses etc. also influence the duration of emptying of the vessel.

The four buttons next to the input field allow the choice of the correct vessel size with its necessary minimal vessel emptying duration pre-set at the factory.

NOTICE!

The value set for the duration of vessel emptying must never go below the pre-determined values for each vessel size set at the factory.

Option water leak detector

If the optional water leak detector is present, its operating method can be set in the submenu *Global*.

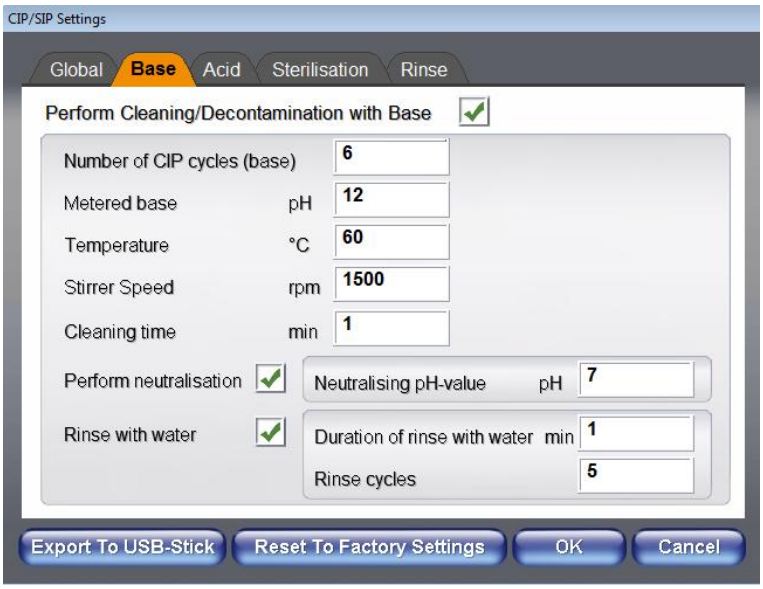
The submenu additionally contains the following in that case:

- Description *On water leak detection show an alarm*
- Optional Function *And Abort Process* with check box*:* Additionally, immediately abort the CIP/SIP process and reset all valves to their idle state.

  The additional function of the immediate process abortion is switched on by activating the check box.

  This operating method of the detector is set at the factory for safety reasons, because the CIP/SIP process usually runs at night and without supervision.

8.4.2 Submenu Base – Cleaning with Base



The submenu *Base* contains check boxes and input fields for configuration of the 1st process phase cleaning / decontamination with base.

The process phase itself or different process sequences only can be switched on or off by activating or deactivating the different check boxes.

The following settings are made here:

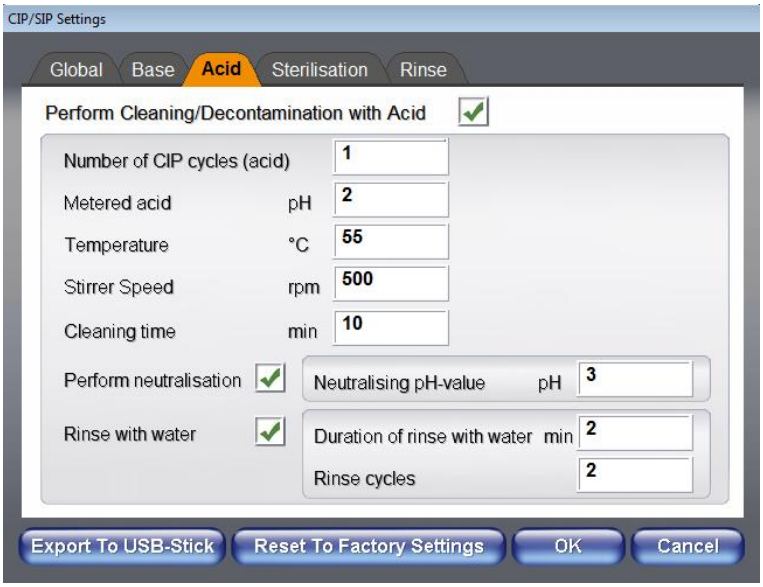
- *Perform Cleaning / Decontamination with base:* to switch the function for cleaning / decontamination with base on or off.
- *Number of CIP cycles (base):* to set the number of cleaning cycles with base.
  Setting range: 1 up to 10 cycles
- *Metered base, pH:* to set the pH setpoint for addition of liquid base.
  Setting range: pH 1 up to 14
- *Temperature, °C:* to set the cleaning temperature.
  Setting range: 20 up to 60 °C
- *Stirrer Speed, rpm:* to set the stirrer rotation speed.
  Setting range: 100 up to 1500 rpm

NOTICE!

Note the different ranges of rotation speed according to the different vessel sizes and drive systems. For details see the chapter "Ranges of Rotation Speed" of the main chapter "Technical Data".

- *Cleaning time, min:* to set the duration of the cleaning cycle in minutes.
  Setting range: 1 up to 120 minutes
- *Perform neutralisation:* to switch the function for neutralisation with acid on or off.
- *Neutralising pH-value, pH:* to set the pH setpoint for neutralisation.
  Setting range: pH 1 up to 14
- *Rinse with water:* to switch the function for rinsing with water on or off.
- *Duration of rinse with water,* min: to set the duration of the rinse cycle with water in minutes.
  Setting range: 1 up to 5 minutes
- *Rinse cycles*: to set the number of rinse cycles with water.
  Setting range: 1 up to 10 cycles

8.4.3 Submenu Acid – Cleaning with Acid



The submenu *Acid* contains check boxes and input fields for configuration of the 2nd process phase cleaning / decontamination with acid.

The process phase itself or different process sequences only can be switched on or off by activating or deactivating the different check boxes.

The following settings are made here:

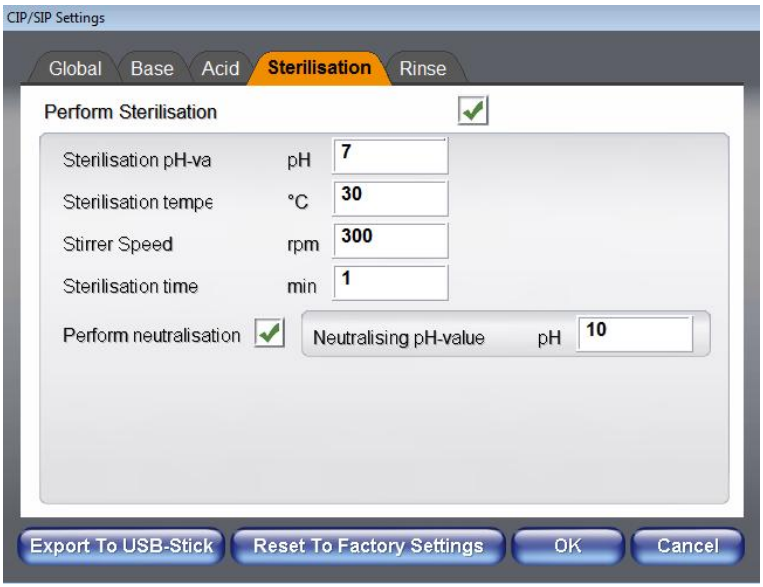
- *Perform Cleaning / Decontamination with acid:* to switch the function for cleaning / decontamination with acid on or off.
- *Number of CIP cycles (acid):* to set the number of cleaning cycles with acid.
  Setting range: 1 up to 10 cycles
- *Metered acid, pH:* to set the pH setpoint for addition of liquid acid.
  Setting range: pH 1 up to 14
- *Temperature, °C:* to set the cleaning temperature.
  Setting range: 20 up to 60 °C
- *Stirrer Speed, rpm:* to set the stirrer rotation speed.
  Setting range: 100 up to 1500 rpm

NOTICE!

Note the different ranges of rotation speed according to the different vessel sizes and drive systems. For details see the chapter "Ranges of Rotation Speed" of the main chapter "Technical Data".

- *Cleaning time, min:* to set the duration of the cleaning cycle in minutes.
  Setting range: 1 up to 120 minutes
- *Perform neutralisation:* to switch the function for neutralisation with base on or off.
- *Neutralising pH-value, pH:* to set the pH setpoint for neutralisation.
  Setting range: pH 1 up to 14
- *Rinse with water:* to switch the function for rinsing with water on or off.
- *Duration of rinse with water, min:* to set the duration of the rinse cycle with water in minutes.
  Setting range: 1 up to 5 minutes
- *Rinse cycles*: to set the number of rinse cycles with water.
  Setting range: 1 up to 10 cycles

8.4.4 Submenu Sterilisation



The submenu *Sterilisation* contains check boxes and input fields for configuration of the 3rd process phase sterilisation

The process phase itself or the process sequence neutralisation can be switched on or off by activating or deactivating the different check boxes.

The following settings are made here:

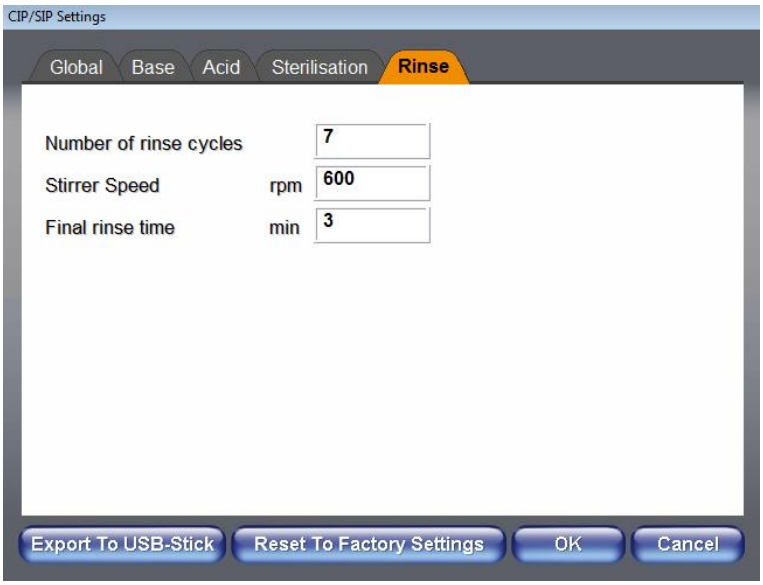
- *Perform Sterilisation:* to switch the function for sterilisation on or off.
- *Sterilisation pH-val, pH:* to set the pH setpoint for sterilisation. Setting range: pH 1 up to 14
- *Sterilisation Tempe, °C:* to set the sterilisation temperature. Setting range: 20 up to 60 °C
- *Stirrer Speed, rpm:* to set the stirrer rotation speed. Setting range: 100 up to 1500 rpm

NOTICE!

Note the different ranges of rotation speed according to the different vessel sizes and drive systems. For details see the chapter "Ranges of Rotation Speed" of the main chapter "Technical Data".

- *Sterilisation time, min:* to set the duration of the sterilisation in minutes.
  Setting range: 1 up to 120 minutes
- *Perform neutralisation:* to switch the function for neutralisation with base on or off.
- *Neutralising pH-value, pH:* to set the pH setpoint for neutralisation
  Setting range: pH 1 up to 14 pH

8.4.5 Submenu Rinse – Final Rinsing with Water



The submenu *Rinse* contains input fields for configuration of the 4th process phase final rinsing with water.

This process phase cannot be switched off.

The following settings are made here:

- *Number of rinse cycles:* to set the number of rinse cycles with water
  Setting range: 1 up to 10 cycles
- *Stirrer Speed, rpm:* to set the stirrer rotation speed
  Setting range: 100 up to 1500 rpm

> *NOTICE!*
>
> *Note the different ranges of rotation speed according to the different vessel sizes and drive systems. For details see the chapter "Ranges of Rotation Speed" of the main chapter "Technical Data".*

- *Final rinse time, min:* to set the duration of the final rinse cycle with water in minutes
  Setting range: 1 up to 5 minutes

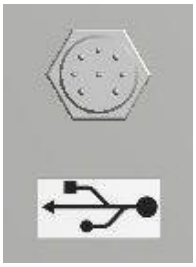
8.4.6 Export to USB-Stick Function

The *Export to USB-Stick* function enables to store the setting values of the configuration menu on a USB stick.
The storage procedure is started in the configuration menu using the **Export to USB-Stick** button.
The function is only available when the CIP/SIP process is stopped. The configuration menu and the **Export to USB-Stick** button are visible but not available during a running CIP/SIP process.

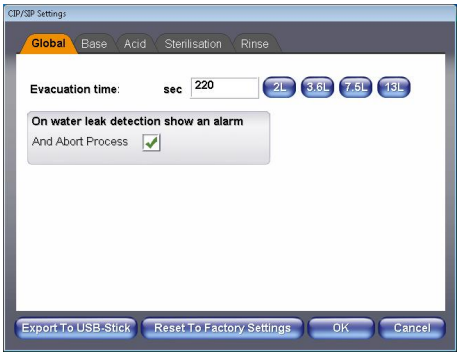
8.4.6.1 Storing the Settings on an USB Stick

To store the settings of the configuration menu on an USB stick, proceed as follows:

Procedure



1. Connect the USB cable to the appropriate connector on the rear side of the touch screen operating panel.
   The USB cable is included in the scope of delivery of the bioreactor Labfors 5.
2. Connect a USB stick to the cable.
3. Log on to the system on the touch screen operating panel on user level *Administrator*.
4. Go to main menu *System* and touch the **SETTINGS** button to call up the submenu *Settings*.
5. Touch the **CIP/SIP settings** button to call up the configuration menu.



The configuration menu opens, the submenu *Global* is automatically selected.

6. Touch the Export to USB-Stick button.

The colour of the **Export USB-Stick** button changes from blue to orange and is flashing during the storage procedure on the USB stick.

When saving is complete, the colour of the button changes again to blue, the flashing stops.

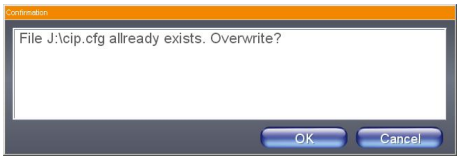
7. Remove the USB stick.

8.4.6.2 Export to USB-Stick Function: Error Messages

If the function is activated before connection of a USB stick, the dialogue box *Confirmation* appears. It contains:

- Prompt *Please insert a removable disk*
- **OK** button: to confirm reading and close the dialogue box.

Once the data are saved on the USB stick, the dialogue box *Confirmation* appears. It contains:



- Question *File x\:cip.cfg already exists. Overwrite?*
- **OK** button: to overwrite the file and close the dialogue box.
- **Cancel** button: to close the dialogue box without changes

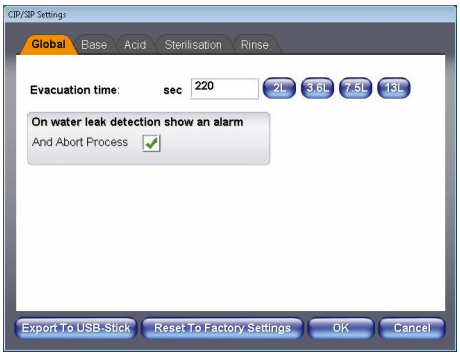
8.4.7 Reset to Factory Settings Function

The *Reset to factory settings* function enables to reset all values in the configuration menu at once to factory settings.
The function is only available when the CIP/SIP process is stopped. The configuration menu and the **Reset to factory settings** button are visible but not available during a running CIP/SIP process.

8.4.7.1 Resetting Values to Factory Settings in Configuration Menu

To reset all values in the configuration menu to factory settings at once, proceed as follows:

Procedure



1. Log on to the system on the touch screen operating panel on user level *Administrator*.
2. Go to main menu *System* and touch the **SETTINGS** button to call up the submenu *Settings*.
3. Touch the **CIP/SIP settings** button to call up the configuration menu.

   The configuration menu opens, the submenu *Global* is automatically selected.
4. Touch the **Reset to factory settings** button.

Operation

The *Confirmation* dialogue box appears. It contains:

- Question *Are you sure to reset the CIP/SIP configuration to factory settings?*
- Warning *All changes will be deleted!*
- **OK** button: to perform the reset and close the dialogue box
- **Cancel** button: to close the dialogue box without changes

5. Touch the **OK** button.

All values are reset to the factory settings, the dialogue box is closed.

8.5 Factory Settings Submenus

The following chapters contain tables with the values set at the factory for each submenu.

8.5.1 Factory Settings Submenu Global

These are the factory settings:

Vessel Size	Emptying duration *(Evacuation time)*
2 litres	220 seconds
3.6 litres	360 seconds
7.5 litres	800 seconds
13 litres	1300 seconds

NOTICE!
Do not use lower values than stated in this table.

Option water leak detector

The operating method of triggering an alarm and immediate abortion of the CIP/SIP process after liquid detection iss et at the factory. This is for safety reasons, because the process usually runs at night and without supervision.

8.5.2 Factory Settings Submenu Base

These are the factory settings:

Function / Input field		Value
Perform Cleaning / Decontamination with base		ON
Number of CIP cycles (base)		2
Metered base (pH setpoint for base addition)	pH	12.5
Temperature (Cleaning temperature)	°C	60
Stirrer Speed	rpm	*Depends on vessel size & stirrer drive, see chapter factory settings stirrer speed*
Cleaning time (Duration of the cleaning cycle)	min	30
Perform neutralisation (Neutralisation with acid)		ON
Neutralising pH-value (pH setpoint for neutralisation)	pH	7
Rinse with water (Perform rinse cycle with water)		ON
Duration of rinse with water	min	2
Rinse cycles (Number of rinse cycles with water)		1

8.5.3 Factory Settings Submenu Acid

These are the factory settings:

Function / Input field		Value
Perform Cleaning / Decontamination with acid		OFF
Number of CIP cycles (acid)		0
Metered acid (pH setpoint for acid addition)	pH	2.5
Temperature (Cleaning temperature)	°C	60
Stirrer Speed	rpm	*Depends on vessel size & stirrer drive, see chapter factory settings stirrer speed*
Cleaning time (Duration of the cleaning cycle)	min	30
Perform neutralisation (Neutralisation with base)		OFF
Neutralising pH-value (pH setpoint for neutralisation)	pH	7
Rinse with water (Perform rinse cycle with water)		OFF
Duration of rinse with water	min	2
Rinse cycles (Number of rinse cycles with water)		1

8.5.4 Factory Settings Submenu Sterilisation

These are the factory settings:

Function / Input field		Value
Perform Sterilisation		ON
Sterilisation pH-val (pH setpoint for sterilisation)	pH	12,5
Sterilisation Tempe (Sterilisation temperature)	°C	60
Stirrer Speed	rpm	300*
Sterilisation time (Duration of sterilisation)	min	120
Perform neutralisation (Neutralisation with acid)		EIN
Neutralising pH-value (pH setpoint for neutralisation)	pH	7

**Applies to all vessel sizes*

8.5.5 Factory Settings Submenu Rinse

These are the factory settings:

Function / Input field		Value
Number of rinse cycles (Number of rinse cycles with water)		3
Stirrer Speed	rpm	*Depends on vessel size & stirrer drive, see chapter factory settings stirrer speed*
Final rinse time (Duration of the final rinse cycle with water)	min	3

8.5.6 Factory Settings Stirrer Speed

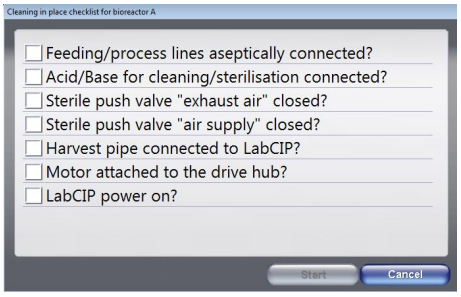
The stirrer speed set at the factory depends on the vessel size and the stirrer drive of the bioreactor Labfors 5. The values stated in the table below apply to each submenu.

Vessel Total Volume	Vessel Diameter	Standard	High Torque
2.0 L & 3.6 L	115 mm	1200 rpm	1200 rpm
3.6 L & 7.5 L	150 mm	1000 rpm	1200 rpm
13 L	200 mm	600 rpm	1000 rpm

8.6 Starting the CIP/SIP Process

The CIP/SIP process is started in the main menu Batch using the **Perform CIP/SIP** button. Process start is possible on all user levels, except for user level *Guest*.

> *NOTICE!*
>
> *A detailed description of the touch screen operating and control panes can be found in the operating manual of the bioreactor Labfors 5.*



After touching the **Perform CIP/SIP** button the dialogue box *Cleaning in place checklist for bioreactor [A –F]* appears. It contains:

- A checklist with questions and check boxes
- **Start** button: to start the process
- **Cancel** button: to close the dialogue box without changes.

> *NOTICE!*
>
> *The Start button is available after all questions in the checklist have been answered with yes, i.e. the check boxes are activated/checked.*

The checklist contains the following questions:

- *Feeding/process lines aseptically connected?*
- *Acid/Base for cleaning/sterilisation connected?*
- *Sterile push valve exhaust air closed?*
- *Sterile push valve air supply closed?*
- *Harvest pipe connected to LabCIP?*
- *Motor attached to the drive hub?*
- *LabCIP power on?*

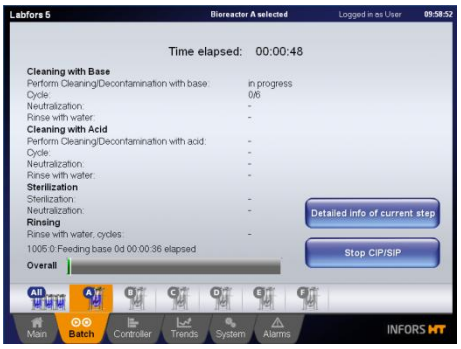
After checking and ensuring all these points and ticking the check boxes by touching them, the CIP/SIP process can be started via the **Start** button in the dialogue box.

NOTICE!

Recommended by the manufacturer:

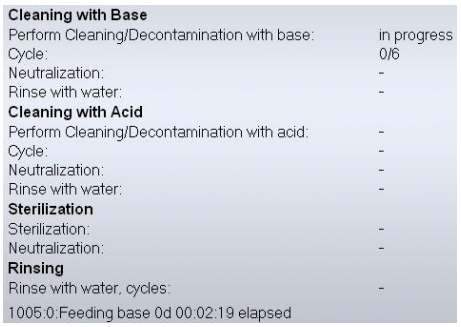
- *Check whether the first vessel filling sequence has worked properly.*
- *Record the CIP/SIP process by using the parallel bioprocess control software Iris from the manufacturer.*

8.6.1 Overview of CIP/SIP Process Development



As soon as the CIP/SIP process has been started, the process development is displayed in a complete overview in the main menu *Batch*.

The elapsed time of the CIP/SIP process in h/min/s is displayed centrally at the top of the screen next to the description *Time elapsed*.



In the centre and left half of the screen all four process phases are listed with the key process sequences. Current process sequences are indicated by *in progress*.

The number of cleaning and rinse cycles currently in progress and the total number of cleaning and rinse cycles to be carried out in process phases 1, 2 and 4 are displayed in the rows called *Cycle*.

In the lowest row beneath all process phases, the process phase currently in progress is displayed with the associated number, name and the elapsed time in d/h/min/s.

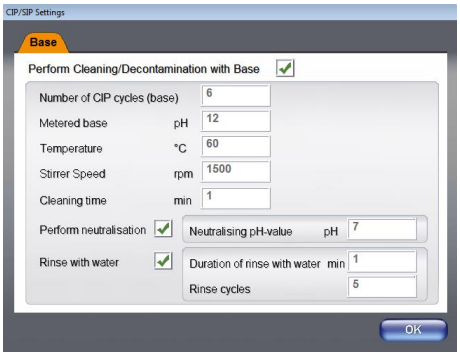
At the bottom left of the screen, the progress of the CIP/SIP process is displayed visually in green after the description *Overall* in a grey bar labelled as a scale from 0 % to 100 %.

In the bottom right-hand half of the screen you will find the following buttons:

- **Detailed info of current step** button: access detailed information of the current process phase.
- **Stop CIP/SIP** button: cancel the CIP/SIP process.

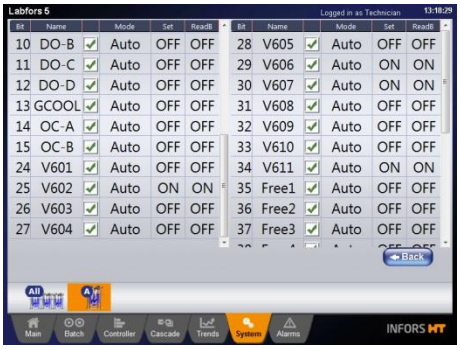
NOTICE!

For details on aborting the process see chapter "Aborting the CIP/SIP Process"



Detailed information of the current process phase is obtained using the **Detailed info of current step** button. This means that the submenu relating to the current process phase appears. All settings can be viewed but not modified. This applies to all user levels.
Touching the **OK** button closes the detailed view.

8.6.2 Overview Valve Positions, Pumps etc.



The submenu VALVES is accessible via the main menu System. Vale positions, pumps, relais, digital inputs and outputs are displayed here. This overview is predominantyl used for fault diagnosis.
In normal mode and with the default factory settings, all digital outputs are set to “Auto” (automatic) mode and should not be changed.

NOTICE!
For details about the submenu VALVES see the operating manual of the bioreactor Labfors 5.

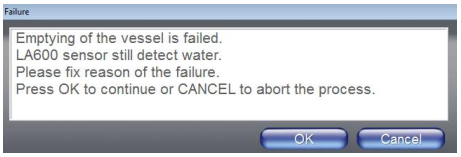
The following table only contains the valves, pumps and inputs/outputs which are relevant for the equipment.

Bit	Name	Description
24	V601	Solenoid valve (NC) / Water inlet
25	V602	Solenoid valve (NC) / CIP/SIP compressed air inlet
26	V603	Solenoid valve (NC) / Exit gas
27	V604	Solenoid valve (NC) / Compressed air to semi-automatic push valve 612 (exit gas cooler)
28	V605	Peristaltic valve (NC) / CIP/SIP circuit
29	V606	Peristaltic valve (NC) / CIP/SIP air inlet and venting
30	V607	Peristaltic valve (NC) / CIP/SIP emptying
31	V608	Peristaltic valve (NC) / CIP/SIP venting
32	V609	Peristaltic valve (NC) / CIP/SIP exit gas
33	V610	Peristaltic valve (NC) / CIP/SIP inlet air

34	V611	Peristaltic valve (NC) / CIP/SIP emptying
35	Free1	Spare output
36	Free2	Spare output
37	Free3	Spare output
38	Free4	Spare output
39	Free5	Spare output
80	LA600	Levels sensor vessel
81	LA601	Level sensor CIP/SIP circuit
82	Switch	If present: optional water leak detector
83	Free1	Spare input
84	Free2	Spare input
85	Free3	Spare input
86	Free4	Spare input
87	Free5	Spare input

8.6.3 Error Message Vessel Emptying

If the emptying of the vessel has failed during one of the process phases, the *Failure* dialogue box appears. It contains:



- Information: *Emptying of the vessel is failed*
- Information: *LA600 sensor (vessel level sensor) still detects water*
- Instruction: *Please fix reason of the failure*
- Instruction: *Press OK to continue or CANCEL to abort the process*
- **OK** button: to continue the process
- **Cancel** button: to abort the process

NOTICE!

For details about possible causes and trouble shooting see the chapter “Vessel emptying has failed” and chapter “Vessel emptying has failed during final rinse” of the main chapter “Interferences”.

8.6.1 Process End

CAUTION!
Risk of injury from leaking corrosive liquid!
If there is a leak in the equipment's hose system, corrosive liquid can escape and collect in the base tray.

If the equipment does not have a water leak detector fitted (optional), you should check at the end of the process whether there is any liquid in the drip tray. If this is the case, this indicates a leak in the hose system. The sterility of the system can no longer be guaranteed.

All the hoses and hose connectors now need to be checked for tightness.

If you have found a leak and it has been remedied, the process should be repeated.

8.7 Aborting the CIP/SIP Process

The running CIP/SIP process can be aborted at any time using the **Stop CIP/SIP** button in the main menu *Batch*.

There exist three different process abortions:

Safe

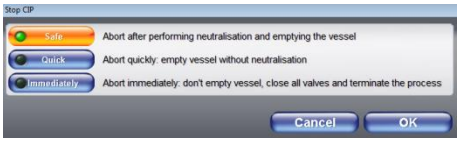
Safe process abortion with neutralisation.
The process continues until the liquid in the vessel and in the circuit is neutralised via the temperature and pH control. Only then the emptying of the vessel begins.

Quick

Quick process abortion without neutralisation.
The running process sequence is immediately aborted; the emptying of the vessel begins.

Immediate

The running process sequence is immediately aborted, all valves are closed, emptying of the vessel is not executed.



Which kind of process abortion should be started, is defined in the *Stop CIP* dialogue box which appears after touching the **Stop CIP/SIP** button. It contains the following buttons:

- **Safe** and description *Abort after performing neutralisation and emptying the vessel*
- **Quick** and description *Abort quickly: empty vessel without neutralisation*
- **Immediately** and description Abort immediately: don't empty vessel, close all valves and terminate the process
- **Cancel**: to close the dialogue box without aborting the

process at all.

- **OK**: to confirm and execute the selected process abortion

No matter which kind of process abortion was chosen, it will be indicated with *aborted at* with date and time below the **Perform CIP/SIP** button at the end.

9 Maintenance

9.1 Safety

Personnel

- The here described maintenance work can be carried out by the user (see “Maintenance plan”).
- Any work on the electrical system is strictly to be carried out by qualified electricians.

Maintenance work, carried out inappropriately

WARNING!
Risk of injury due to maintenance work carried out inappropriately!

Maintenance work carried out inappropriately may lead to severe physical injury or loss of property:

Therefore:

– Make sure that enough space is provided for the work before starting.
– Keep the work site tidy and clean! Discarded components and tools may be a source of accidents.
– Check correct re-assembly if component parts have been previously removed. Re-assemble all components for securing housings etc. correctly and adhere to the stated torque when tightening screws.
– Strictly follow internal safety regulations.

Electrical system

DANGER!
Danger of fatal electric shock!

Contact with electrically powered components is perilous. Energised electrical components may perform uncontrolled movements which can lead to severe injuries.

Therefore:

– Turn off the electrical supply and check whether it is electrically isolated before starting any work.

Biohazard

WARNING!
Biohazard!

Noncompliance with biological safety regulations increases the health risk of the operator and the risk of lower equipment functionality.

Therefore:

– Strictly follow all biological safety regulations
– Decontaminate and sterilise every part including any peripheral in- and outlet that comes in contact with any infectious biochemical substances (e.g. liquids which contain bacteria or viruses).
– Dispose of medium according to the local regulations – sterilised medium only!

WARNING!
Health risk due to contaminated component parts!

Contact with contaminated component parts contains a health risk due to viruses and bacteria.

Therefore:

– Strictly follow working instructions.
– Strictly follow cleaning sterilisation instructions of component parts.

9.2 Environmental Protection

CAUTION!
Environmental danger by inappropriate handling!

Inappropriate handling of environmentally hazardous substances, especially where disposal is involved, may lead to severe environmental damage.

Therefore:

– Immediately take appropriate action if environmentally hazardous substances are accidentally released into the environment.

9.3 Maintenance Plan

The required maintenance for reliable operation is described in the following chapters.

Reduce the maintenance intervals in case increased abrasion is detected during regular checks.

Contact the manufacturer for questions concerning maintenance. For contact details, see page 2.

Interval	Maintenance work	To carry out by
Before every CIP/SIP process run	Check supply and connection lines, hose tree and reagent bottle hoses and pump hoses for damage, change if necessary.	User
	Check that O-rings on semi-automatic push valves and all vessel components or in vessel top plate ports are in place and intact and replace if necessary.	User
	Check acid/base reagent bottles for damage such as hairline cracks, scratches etc., replace if necessary. The same applies to the reagent bottles for the bioprocess and the culture vessel of the bioreactor.	User
After 5 CIP/SIP process runs	Dismantle semi-automatic push valves (in particular the exit gas cooler push valve), check for contamination, clean if necessary. Check O-rings and piston seals for damage and wear, replace if necessary.	User
After 30 CIP/SIP process runs or every 6 months	Replace exit gas filter	User
	Replace hose tree	User
	Replace pump hoses (only complete pump head including pump head can be changed)	User
	Replace water filter	User
	Replace reagent bottle (acid / base) hoses	User
As required	Adjust sensitivity of the vessel level sensor (LA600)	User
	Clean equipment surfaces.	User
	OPTION: Wipe the contact surface of the optional water leak detector (LA602) with a damp cloth	User

NOTICE!

All information on maintenance work on the bioreactor and its accessories is described in the bioreactor operating manual.

9.4 Replacing Reagent Bottle Hoses and Pump Heads

CAUTION!
Danger due to corrosive residual fluid in the hoses!

When removing the hoses from the acid and base reagent bottles and the pump hoses, acid or base may escape.

Therefore:

– Always wear safety glasses and chemical-resistant protective gloves.

NOTICE!

A pump hose must be replaced including the pump head and vice versa.

To replace the reagent bottle hoses and the pump hoses or pump heads, proceed as follows:

Procedure

1. Remove the hoses from the reagent bottle and from the double inlet needle.
2. Remove the pump heads from the motor shafts on the basic unit of the bioreactor.
3. Dispose of the hoses and pump heads in accordance with internal safety regulations.
4. Fit new hoses to the reagent bottles and connect to new pump heads. For details see the chapter “Preparing the Acid/Base Reagent Bottles” in the main chapter “Preparations for Use”.

9.5 Replacing the Water Filter

The water filter should be replaced after 30 CIP/SIP process runs or after 6 months.

CAUTION!
Danger due to corrosive residual fluid in the water filter!

When replacing the water filter, corrosive residual fluid may escape.

Therefore:

– Wear safety glasses and chemical-resistant protective gloves.

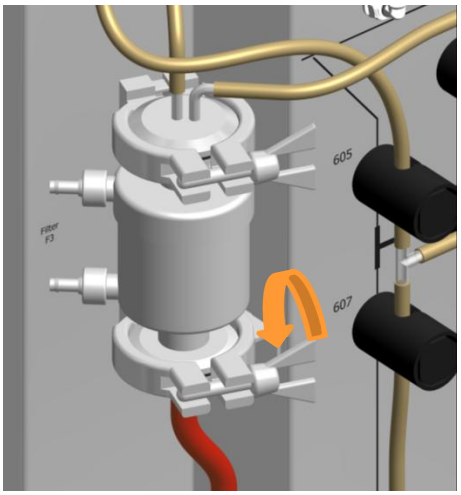
Before replacing the water filter check and ensure the following:

- The equipment and bioreactor are turned off at the main switch.
- The water and air are turned off, supply lines are depressurised.

Removing the old filter

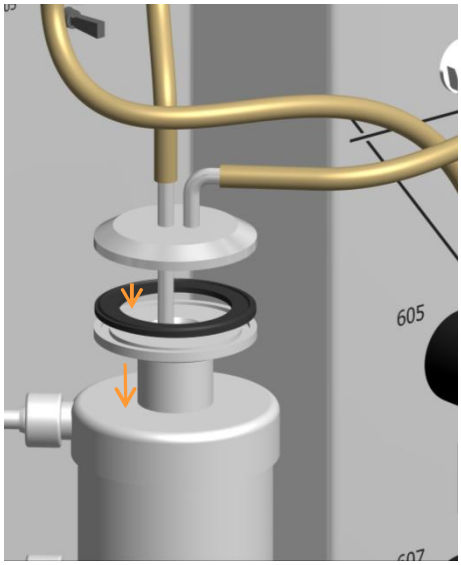
Proceed as follows:

Procedure



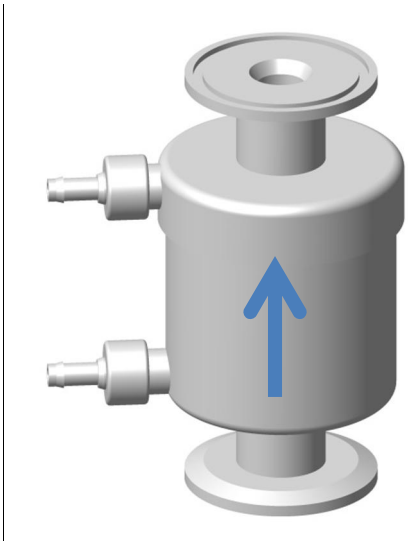
1. Remove the front door from the equipment.
2. Loosen and unhook the wing bolt on the lower clamp on the water filter.

   The clamp is firmly connected to the equipment holder.
3. Remove the hose line with flange and flat seal from the lower connecting flange of the water filter.
   Ensure that the flat seal doesn't get lost!



4. Loosen and unhook the wing bolt on the upper clamp on the water filter.
5. Remove the clamp.
6. Remove the water filter and flat seal from the upper hose line with flange and dip tube.
   Ensure that the flat seal doesn't get lost!
7. Check both flat seals for damage, replace if necessary.

Installing the new water filter



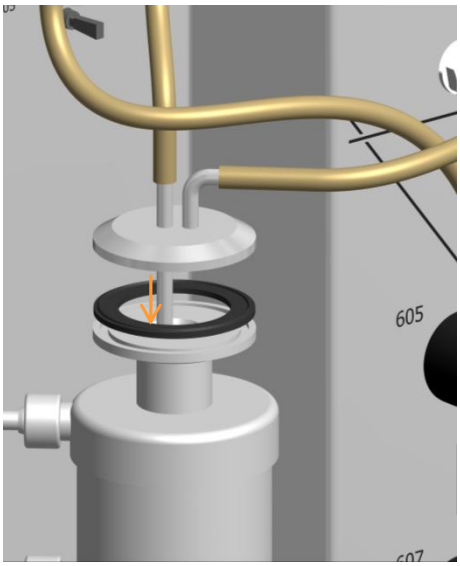
Before installation, note the correct orientation of the water filter:

- The flow direction of the filter is marked with an arrow on the filter. Water/liquid flows from the bottom to the top through the filter in the hose tree.
- Lateral valves on the water filter point to the housing wall

For installation, proceed as follows:

Maintenance

Procedure



1. Place the flat seal flush on the upper connecting flange of the water filter.
2. Insert the dip tube in the water filter and place the flange of the hose line flush to the connecting flange of the water filter.
3. Put the clamp around the connecting flange, insert the wing bolt and screw in tight.
4. Place the flat seal flush on the flange on the lower hose line.
5. Place the lower connecting flange of the water filter flush on the flange and the flat seal on the hose line.
6. Put the clamp around the connecting flange, insert the wing bolt and screw in tight.
7. Remount the front door of the equipment.

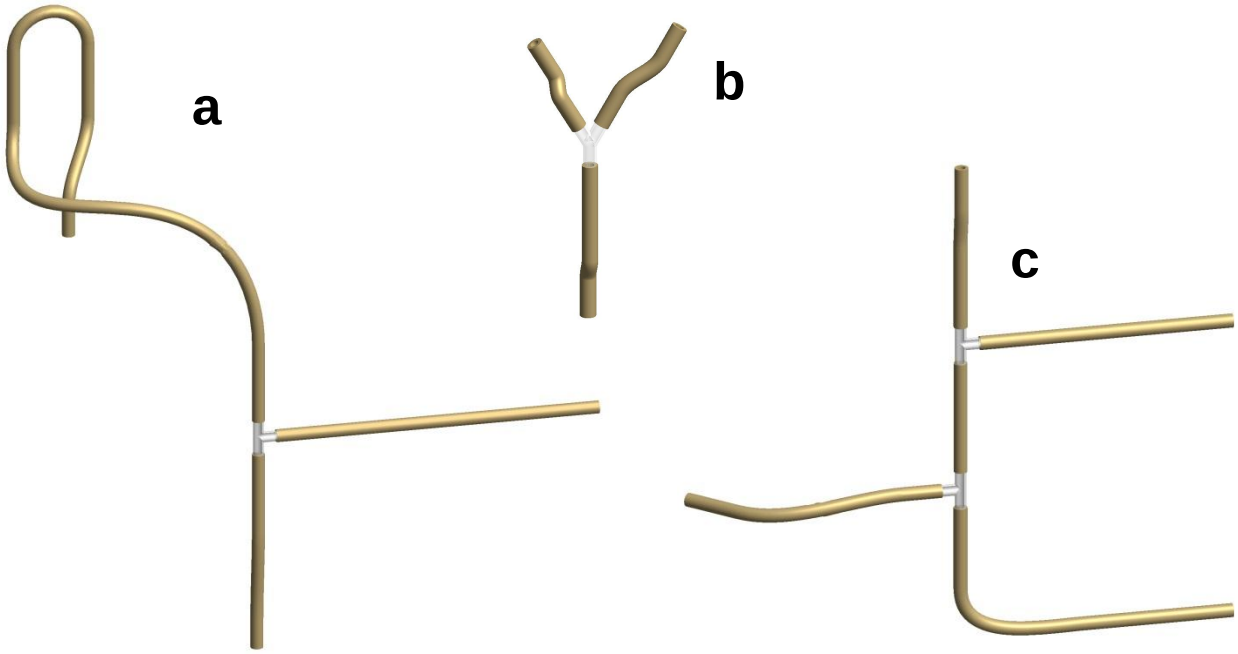
NOTICE!

For the first vessel filling sequence of the CIP/SIP process after changing the filter, vent the filter by opening the top valve.

9.6 Replacing the Hose Tree

The hosing undergoes an ageing process as a result of using acids and bases. To prevent damage as a result of leakage, the equipment hose tree must be replaced after 30 CIP/SIP process runs or after 6 months.

The hose tree is available as a three-part hose set. The three parts of the hose tree are pre-fitted with T-pieces. Cable ties for securing the hoses are included in the set.



a) Connection to pump, water filter and harvest pipe

b) Connection to circuit level sensor (LA601) and hose pinch valve 608

c) Connection to circuit level sensor (LA601), exit gas cooler, water filter and air pipe (sparger)

9.6.1 Changing the Hose Tree

CAUTION!
Danger due to corrosive residual fluid in the hoses!

When removing the hose tree, corrosive residual fluid can escape from the hoses of the hose tree.

Therefore:

– Always wear safety glasses and chemical-resistant protective gloves.

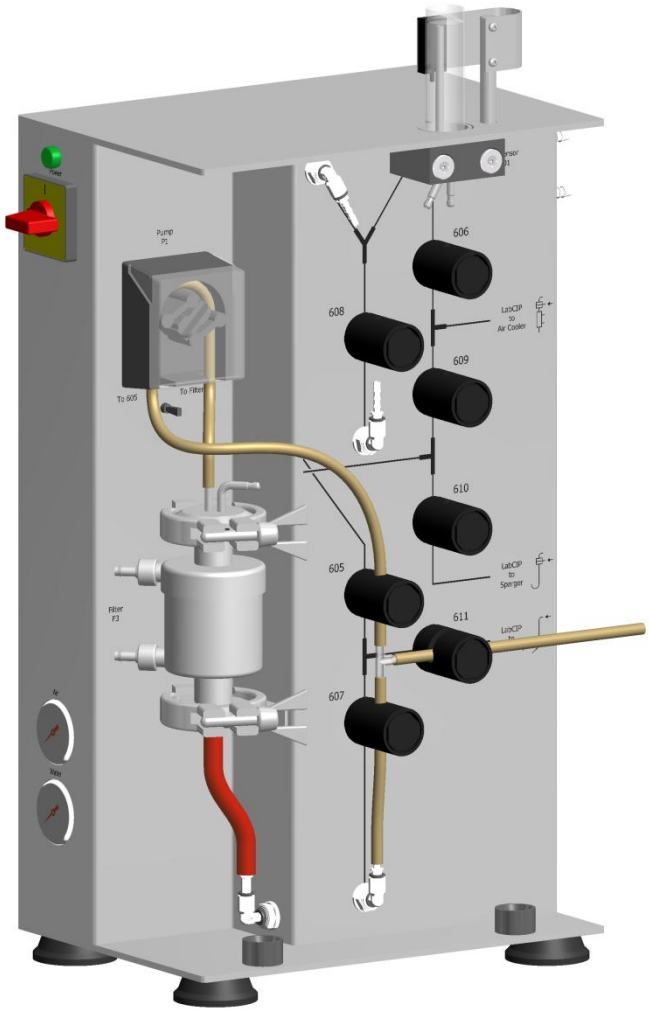
Before changing the hose tree check and ensure the following:

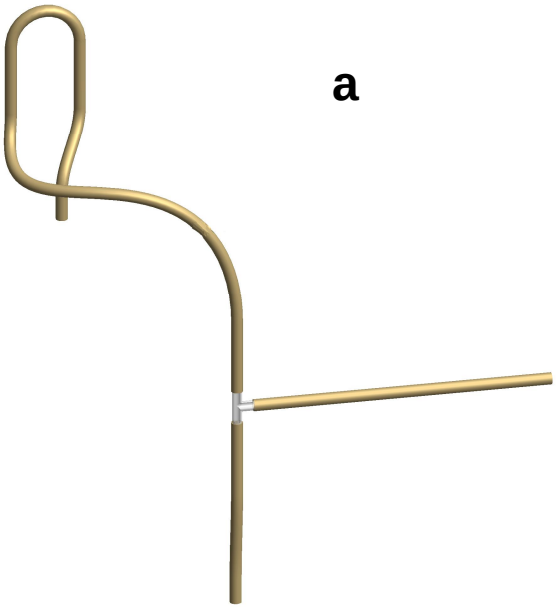
- The equipment and bioreactor are turned off at the main switch.
- The water and air are turned off, supply lines are depressurised.
- All connections between the hose tree on the equipment and the vessel are detached:
  - Hose connection *LabCIP to air cooler* (exit gas cooler connection)
  - Hose connection *LabCIP to sparger* (air pipe connection)
  - Hose connection *LabCIP to harvest pipe* (harvest tube connection)

Procedure

It is easiest to replace each section of the hose tree in turn. The following figures show each section individually and assembled.

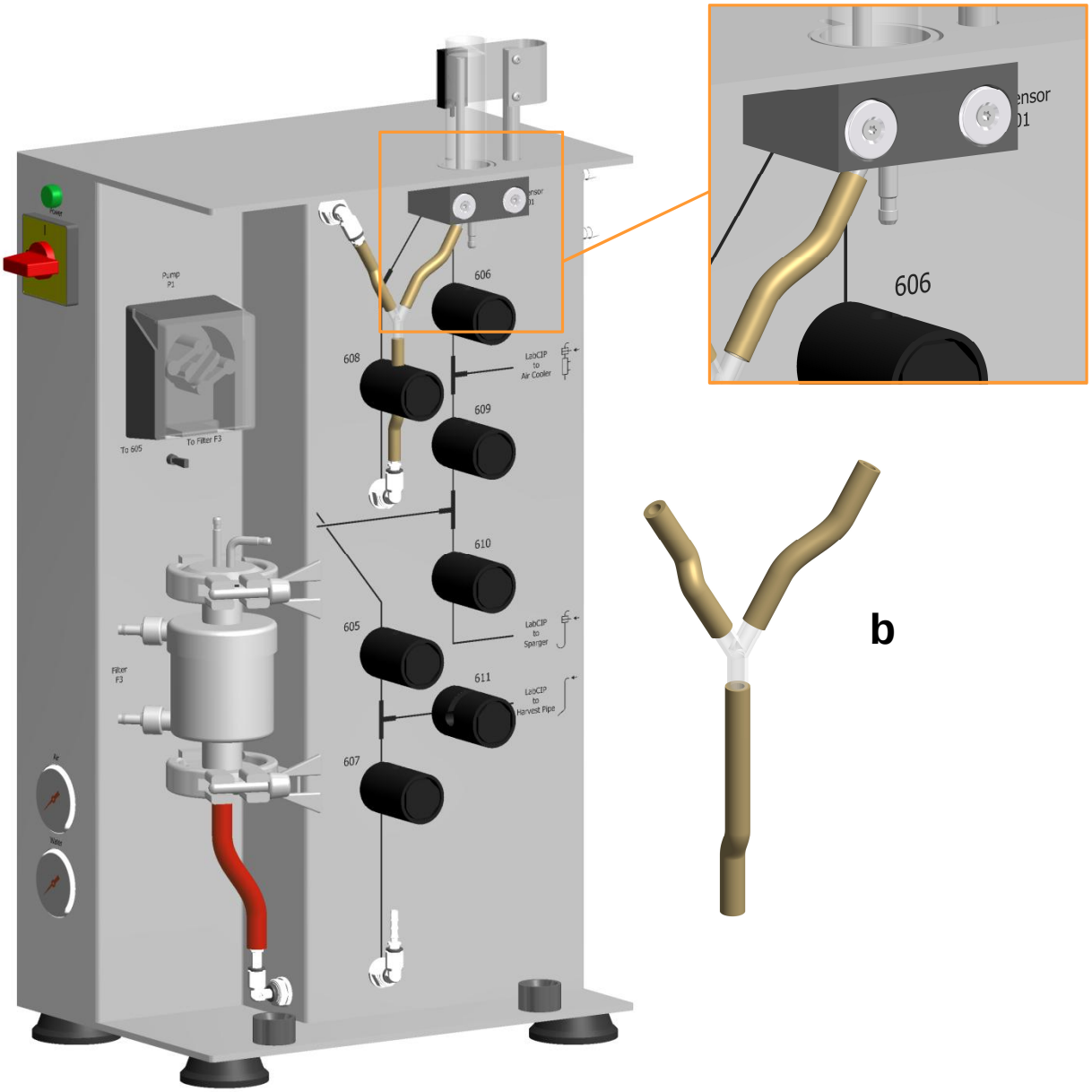
Connection of hose tree section a





Maintenance

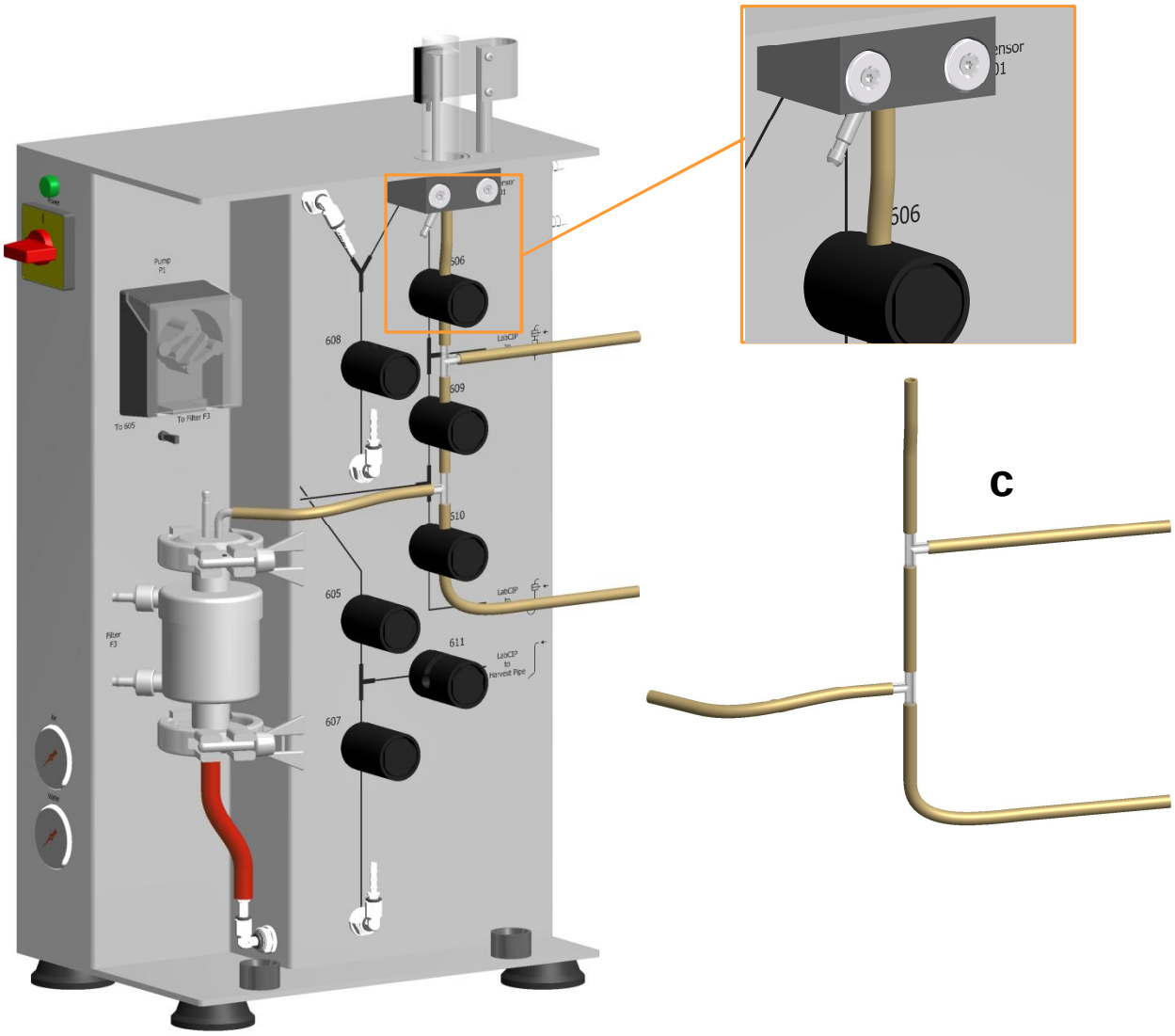
Connection of hose tree section b



NOTICE!

The right-hand hose MUST be connected to the overflow pipe (long pipe with hose nozzle), which protrudes out of the tank.

Connection of hose tree section c

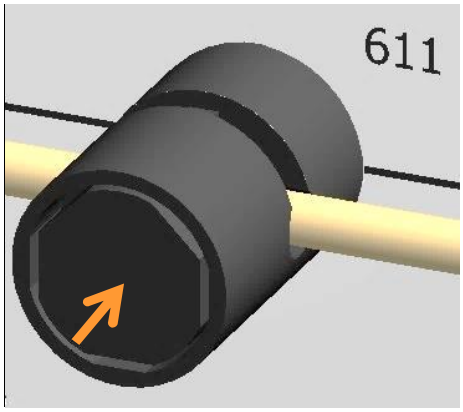


NOTICE!

The top hose MUST be connected to the short pipe with hose nozzle, which protrudes out of the tank.

Maintenance

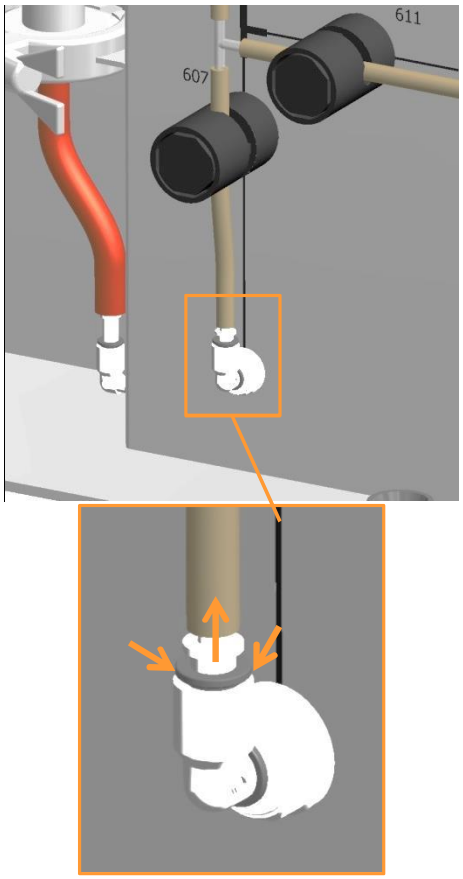
Hose pinch valves



The hoses can easily be removed or inserted by pushing on the valve piston of the hose pinch valves.

Hose nozzles

To make it easier to remove the old and fix the new hoses from / to the hose attachable nozzles, these can be taken out of the bulkhead connections.



- Extracting: press the grey ring evenly towards the bulkhead connection and at the same time, pull out the hose nozzle.

- Inserting: simply put the hose nozzle into the bulkhead connection.

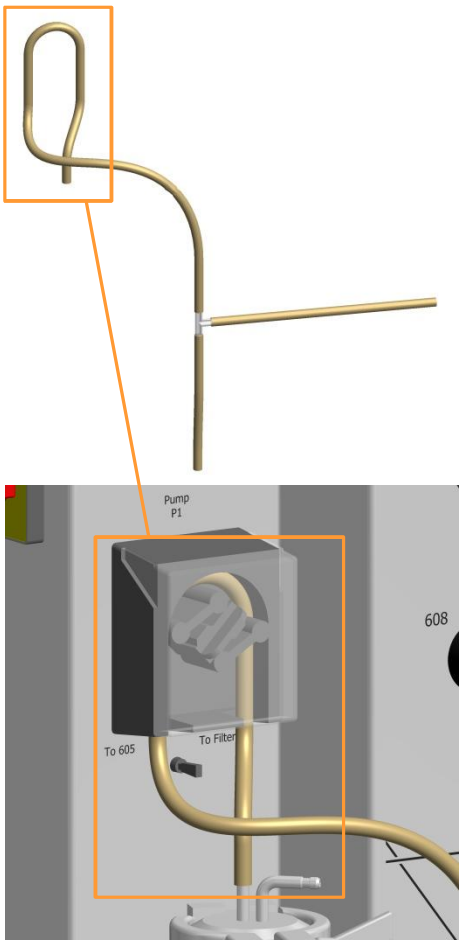
9.6.2 Inserting the Hose into the Pump

CAUTION!
Danger due to electrical pump drive!

If the pump is electrically operated via the rocker switch (only possible if the equipment is switched on) during hose insertion, your fingers can get pinched and the hose damaged.

Therefore:

– Always turn the pump head by hand when inserting the hose.



The hose tree section a must be inserted in the pump. Make sure the hose is routed correctly!

NOTICE!

The following figures provide a general overview. They show another pump and tubing. However, the procedure is the same.

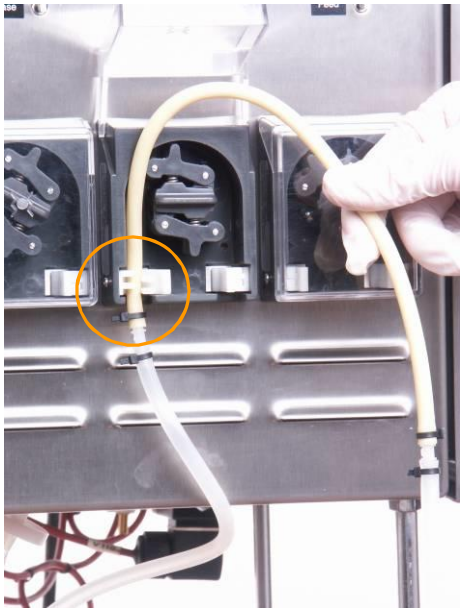
Maintenance

To insert the hose in the pump, proceed as follows:

Procedure

1. Fold up the pump cover.
2. Press the white left-hand clamp inwards and insert the hose at the same time.
3. Release the clamp.

   The hose is now secured by the left clamp.

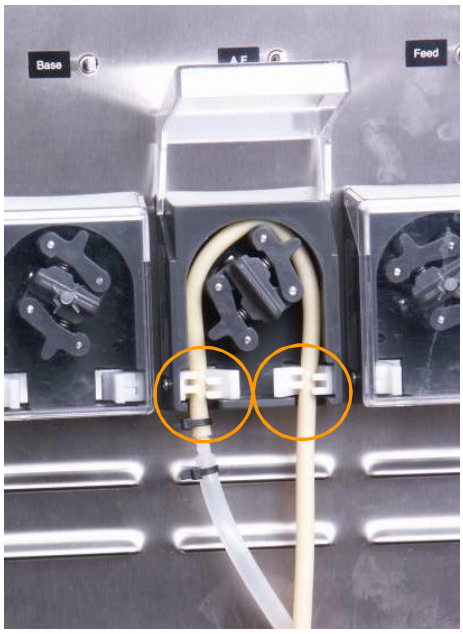


4. Thread the hose around the pump head and push in gently.

5. Slowly turn the pump head clockwise with one hand and guide the hose with the other.

6. Press the white right-hand clamp inwards and insert the hose at the same time.
7. Release the clamp.

   The hose is inserted and is secured by the two clamps.



8. Fold down the pump cover.

9.6.3 Securing Hoses

CAUTION!
Danger due to inadequately secured hoses!

Inadequately secured or unsecured hose ends of the hose tree may come loose from the hose nozzles during operation due to the pressure in the hose lines. Hot, corrosive liquid can escape out of the hoses.

Therefore:

– Always secure the ends of the hose tree hoses with cable ties to the different hose nozzles and connecting parts of the various components.

If all the individual parts of the hose tree are correctly fastened, all the ends of the hoses must be secured using cable ties.

9.7 Adjusting the Sensitivitiy of the Vessel Level Sensor

Tools

Micro screwdriver

To adjust the sensitivity of the vessel level sensor (LA600), proceed as follows:

Procedure

1. Check the position of the vessel level sensor and the position of the top impeller on the stirrer shaft:
   - Vessel level sensor:
     The top edge of the sensor holder is in contact with the lower ring of the vessel holder
     For details see the chapter “Checking the Position of the Vessel Level Sensor” of the main chapter “Preparations for Use”.
   - Top impeller:
     There is a distance of 45 mm between the lower edge of the vessel top plate and the lower edge of the impeller blade.
     For details see the chapter “Checking the Position of the Impellers” of the main chapter “Preparations for Use”.
2. Fill the vessel with water.

   The top impeller is slightly dipped in the liquid.

3. Carefully open the sensor cover.
   The potentiometer, a small screw, is located behind the cover.
4. Turn the screw counter clockwise (to the left) until the LED goes ON on the sensor.
   This signifies that the sensor does not detect any liquid.
5. Turn the screw clockwise (to the right) until the LED goes OFF on the sensor.
   This signifies that the sensor detects some liquid.
6. Gently rock the vessel so that the liquid inside starts to slosh slightly.

   Depending on whether the sensor detects liquid or not, the LED should go ON and OFF.

   Repeat the steps 4, 5 and 6, if necessary.
7. Carefully close the sensor cover.

9.8 Cleaning

9.8.1 Cleaning Agents

CAUTION!
Risk of damage due using of inappropriate cleaning agents!

Using inappropriate cleaning agents may cause loss of property. Also the front door of the equipment made of acrylic glass may be destroyed.

Therefore:

– Never use a glass cleaning product for cleaning the front door.
– Only use manufacturer prescribed cleaning agents as listed in the table below.

Designated use	Permitted products
Housing surfaces (stainless steel)	Mild neutral household detergent
Front door (acrylic glass)	Little commercially available dishwashing detergent on a damp cloth. **No product for glass cleaning!**
Push valves (semi-automatic)	Mild neutral household detergent

9.8.2 Cleaning the Surfaces of the Equipment

DANGER!
Risk of fatal electric shock!

There may be fatal danger by touching electrically powered components. Cleaning when the equipment is switched on may have fatal consequences.

Therefore:

– Switch the equipment off at the main switch and disconnect from mains supply before cleaning.
– Keep humidity away from components which are electrically powered, as excessive moisture may lead to short circuit.

For cleaning the surfaces of the equipment proceed as follows:

Procedure

1. Switch the equipment off at the main switch.
2. Disconnect the equipment from the mains supply.
3. Wipe the housing surfaces (stainless steel) of the equipment with a soft, non-abrasive damp cloth. Use a little mild and neutral household detergent, if necessary.
4. Always wipe dust on the front door made of acrylic glass with a damp and soft cloth. Use little commercially available dishwashing detergent, if necessary. Never wipe it with a dry cloth!
5. Let the equipment dry before reconnection to the mains supply.

NOTICE!

Dirt and slight signs of wear (scratches) on the front door made of acrylic glass may be removed with a polishing agent suitable for polycarbonate and acrylic glass.

9.8.3 Cleaning the Air Pipe and Exit Gas Cooler Push Valves

Contamination may occur over time inside the semi-automatic push valves. This particularly applies to the push valve on the exit gas cooler. For this reason the push valves should be dismantled after 5 CIP/SIP process runs, checked for contamination and if necessary cleaned with a mild neutral cleaner. At the same time, all O-rings and the piston sealing ring should be checked to ensure they are intact and replaced if necessary.

Dismantling

The following tool is required:

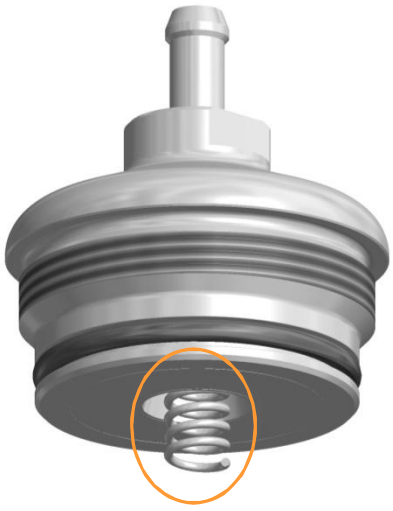
- Open-end wrench, size 13
- Stick (e.g. end of a pencil)

Maintenance

To dismantle a semi-automatic push valve, proceed as follows:

Procedure

1. Hold the valve cylinder tightly by hand and using the open-end wrench, unscrew the valve cover counter clockwise.



The valve cover is now free. The compression spring is automatically lifted off of the centring cam on the valve piston inside the valve cylinder by the ring magnet that is integrated in the valve cover.

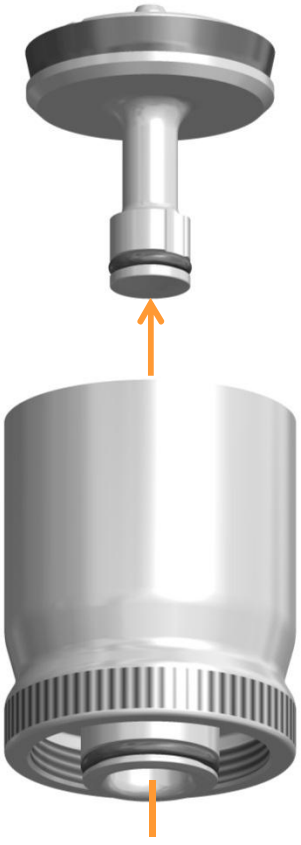
CAUTION!
Danger of material damage due to magnetism!

The strong ring magnet can adversely affect the function of equipment that is sensitive in this way (e.g. watch, measuring instrument) and destroy electronically stored data.

Therefore:

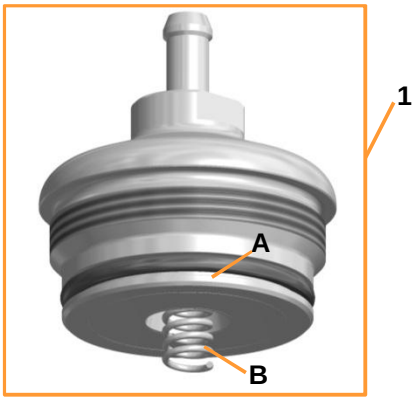
– Keep sensitive equipment and objects away from the valve cover.

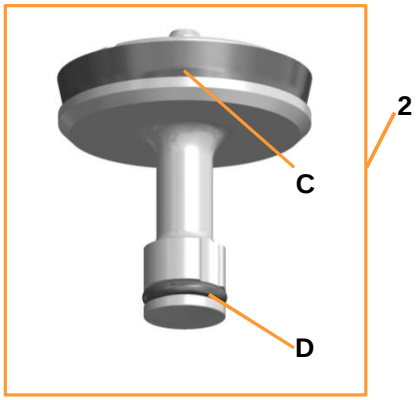
2. Manually push the valve piston into the valve cylinder.

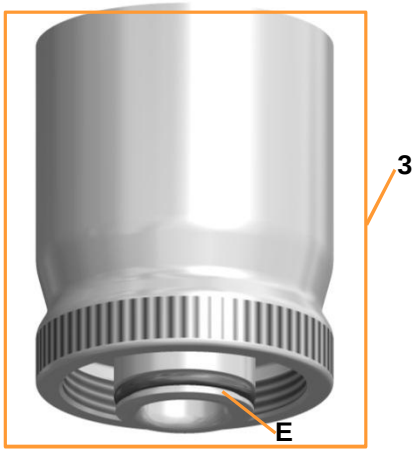


3. With a stick, push the valve piston far enough into the valve cylinder so that it comes away and can be removed from the valve cylinder.

Maintenance







Now the push valve is disassembled into three parts:

1 Valve cover with:
A) O-ring Ø = 2.5 x 31 EPDM
B) Compression spring

2 Valve piston with:
C) Piston sealing ring Ø = 29 x 36 FKM
D) O-ring Ø = 2 x 8 EPDM, coated

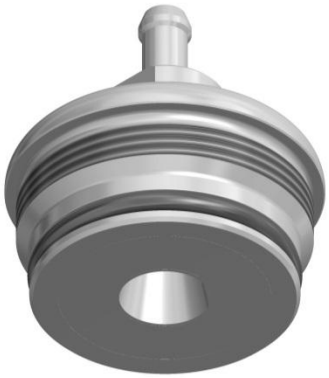
3 Valve cylinder with:
E) O-ring Ø = 2 x 16

Cleaning

For cleaning, proceed as follows:

Procedure

1. Remove the compression spring out of the valve cover and put to one side. Ensure that the compression spring does not get lost!



The left figure shows the valve cover without the compression spring.

2. Clean the inside of the valve cylinder, valve cover and valve piston with a scratch-resistant sponge or a washing-up brush and mild neutral cleaner.
3. Leave the dismantled push valve to dry.
4. Check O-rings and piston seal for damage, replace if necessary.

Assembling

Once the semi-automatic push valves are clean, dry and if necessary, fitted with new O-rings and/or piston seals, they can be reassembled.

To assemble a semi-automatic push valve, proceed as follows:

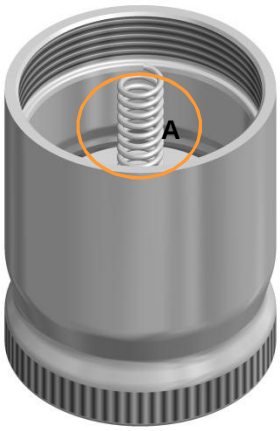
Procedure

1. Insert the valve piston in the valve cylinder and push it entirely through so that the piston protrudes out of the cylinder.

   The push valve is then open.

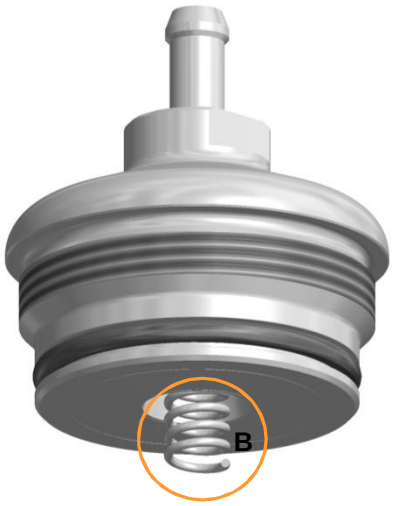
2. Insert compressed spring:

Maintenance



Variant A)
Place the compressed spring on the centring cam on the valve piston.

OR:



Variant B)
Insert the compressed spring in the opening to the valve cover.
The compressed spring is automatically secured in the valve cover by the integrated ring magnet.

CAUTION!
Danger of material damage due to improper assembly!

If the compressed spring does not sit on the centring cam on the valve piston when attaching the valve cover, it is only possible to fasten the valve cover in place tightly using force. This can lead to the compressed spring or thread being damaged. As a result the push valve will leak.

Therefore:

– Carefully fasten the valve cover in place and only if the compressed spring is intact and in the correct position.

3. Place the valve cover on the valve cylinder and manually screw it on a little.
4. Hold the valve cylinder tightly by hand and using the open-end wrench, carefully screw the valve cover clockwise.

NOTICE!

Do not use force when tightening! Signs of resistance may indicate that the compressed spring is not sitting on the centring cam. In this case, unscrew the valve cover again and check the position of the compressed spring, correctly position it if necessary.

10 Interferences

Possible reasons for interference or a problem and how to resolve it is described in the following section.

Contact your Infors contracting partner in case of developing problems which cannot be resolved by following the instructions

10.1 Safety

Personnel

- The here described trouble shooting work may be carried out by the user, if not indicated otherwise (see “Tables of Interferences”).
- Any work on the electrical system is strictly to be carried out by qualified electricians.

CAUTION!
Risk of injury due to inappropriate trouble shooting!

Inappropriate trouble shooting may lead to physical injury or loss of property.

Therefore:

– Strictly follow the trouble shooting instructions stated in this operating manual

10.2 Status Display does not illuminate

Possible cause	Fault rectification	Rectify by
Power cable is not connected.	Check the power cable connection.	User
Main switch is not switched on.	Switch on the main switch.	User
Break in power connection.	Check plug connection. Check mains cable for damage and kinks. Check the socket and cable on the equipment.	Electrician
Fuses blown	Check the mains connection fuses. Check equipment fuse.	Electrician

10.3 Vessel does not fill

Possible cause	Fault rectification	Rectify by
Air pocket in the water filter	Check whether the water filter is filled with water. If only a little or no water is visible in it: Briefly open the top rotary valve to vent the water filter and then reclose the rotary valve.	User
Exit gas line blocked	Check whether the hose piece between the exit gas filter and equipment port *To air cooler* is kinked or pinched. And/or: Check whether the in-house exit gas line (hose from the equipment port *To air waste*) is kinked or pinched.	User
Insufficient or no water supply to the equipment	Check whether the water pressure indicator (*Water* manometer) displays at least 0.5 – 0.6 bar. If NOT: Check whether the water is turned on or the water supply is open. If it is open: check the inlet pressure of the water. If necessary increase the pressure within the tolerance of 2 ± 1 bar. If the inlet pressure is correct: check whether the hose on the water inlet of the equipment is kinked or clamped.	User
Water is not draining or not draining adequately	Check whether the air pressure indicator (*Air* manometer) displays at least 0.5 – 0.6 bar. If NOT: Check whether the hose on the water outlet of the equipment is kinked or clamped. Check whether the in-house water outlet is free of back pressure.	User
The vessel is so heavily contaminated that the level sensor (**LA600**) is permanently activated.	Release the level sensor (**LA600**) from the vessel wall. Wait until the vessel is filled up to the maximum fill level of the vessel. Reattach the level sensor. *For details on the level sensor positioning, see the section "Changing the Position of the Vessel Level Sensor (LA600)" in the main chapter "Preparations for Use".*	User

10.4 Vessel does not fill During Final Rinsing

Possible cause	Fault rectification	Rectify by
The circuit pump (**P1**) is not running correctly or not at all.	Check whether the pump is turning (anticlockwise) If not: Check whether the hose is inserted correctly, if necessary insert correctly. Check the function of the pump manually: Push the rocker switch to the left, pump must turn anticlockwise. If not: Contact your Infors licensed dealer	User

10.5 pH Value is not Achieved

Possible cause	Fault rectification	Rectify by
No or inadequate acid / base addition.	Check whether the reagent bottles are correctly connected to the double inlet needle in the vessel top plate port. Check whether the hoses are clamped or kinked. Check whether the reagent bottles are full. Check whether the reagent bottles are connected in accordance with their content to the correct pump: acid to *Acid* pump / base to *Base* pump.	User
Pump(s) is/are not functioning correctly	Check the function of the pump(s): Activate the *Acid* pump and/or *Base* pump manually using the rocker switches.	User
Pump hose(s) defective	Replace pump head(s)	User

10.6 Vessel Emptying Failed

The error message (dialogue window *Failure*) appears.
(For the content of the error message see the chapter “Error Message – Vessel Emptying” in the main chapter “Operation”.)

Possible cause	Fault rectification	Rectify by
Insufficient or no compressed air supply to the equipment	Check whether the air pressure indicator (*Air* manometer) displays at least 0.5 – 0.6 bar. If NOT: Check whether the compressed air is turned on or the compressed air supply is open. Check whether the hose on the compressed air inlet of the equipment is kinked or clamped. Check the inlet pressure of the compressed air. If necessary increase the pressure within the tolerance of 2 ± 0.5 bar. Continue process in dialogue window *Failure* by touching the **OK** button.	User
Water is not draining or not draining adequately.	Check whether the hose on the water outlet of the equipment is kinked or clamped. Check whether the in-house water outlet is free of back pressure. Continue process in dialogue window *Failure* by touching the **OK** button.	User

10.7 Vessel Emptying Failed During Final Rinsing

The error message (dialogue window *Failure*) appears.
(For the content of the error message see the chapter “Error Message – Vessel Emptying” in the main chapter “Operation”.)

Possible cause	Fault rectification	Rectify by
Push valve on the exit gas cooler has not opened.	**1.** Carefully remove the hose of the *To air cooler* port on the equipment from the exit gas filter. **2.** Fill an empty syringe with air. **3.** Spray air into the exit gas filter. **4.** Reattach the hose to the exit gas filter. **5.** Continue process in dialogue window *Failure* by touching the **OK** button.	User
Valve piston in the push valve on the exit gas cooler is stuck	**1.** Cancel the process in the dialogue window *Failure* by touching the **Cancel** button. **2.** Dismantle, clean, assemble the push valve. **3.** Check the function again manually. **4.** If necessary, replace the push valve.	User

10.8 Max. Flow is not achieved at the End of the Process

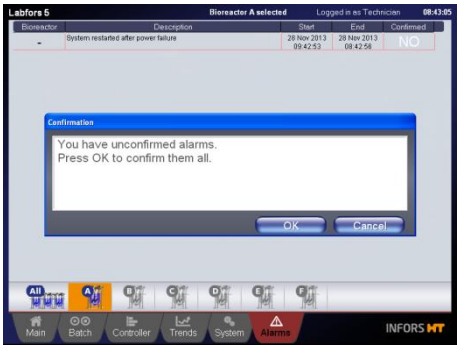
Actual value flow parameter ≠ max. flow mass flow controller

Possible cause	Fault rectification	Rectify by
Push valve on the air pipe has not opened.	If installed: Check whether the rotameter valve is open, if necessary gradually open it fully. If the fault is not remedied: **1.** Carefully pull off the inlet air hose (hose piece between the air/gas supply on the bioreactor basic unit and inlet air filter) from the inlet air filter. **2.** Fill an empty syringe with air. **3.** Spray air into the inlet air filter. **4.** Reattach the inlet air hose to the inlet air filter.	User
Inlet air filter blocked.	**1.** Abort process. **2.** Replace the inlet air filter.	User
Push valve on the air pipe is stuck	**1.** Abort process. **2.** Dismantle, clean, assemble the push valve. **3.** Check the function again manually. **4.** If necessary, replace the push valve.	User

10.9 Power Failure

If the power supply to the bioreactor or the entire plant is interrupted, the CIP/SIP process immediately and automatically stops.

Consequences of the power supply being restored



Power failure alarm appears on the touch screen operating panel

Steps to take once the power supply has been restored

Procedure

1. Confirm *Power Failure* alarm.
2. Check whether there is still liquid in the vessel.
3. Check whether the liquid is still strongly acidic or basic by checking the measured pH value.

   To start automatic vessel emptying with or without neutralisation:
4. Restart the CIP/SIP process.
5. Cancel the CIP/SIP process using the **Stop CIP/SIP** button with or without neutralisation.

If both push valves on the air pipe and exit gas cooler are still closed the CIP/SIP process can then be restarted without any other preparation work.

Steps to take if the power supply cannot be re-established

Procedure

1. Check whether there is still liquid in the vessel.
2. If necessary manually empty the vessel, taking into account in-house safety regulations.
3. Contact Infors licensed dealer.

10.10Power failure, only LabCIP

If only the power supply to the LabCIP equipment is interrupted, the power supply of the bioreactor remains, the CIP/SIP process continues until the next filling or emptying sequence. The process cannot run properly and needs to be restarted once the power supply has been re-established.

Action in the event of power failure

Step

1. Using the **Stop CIP/SIP** button, immediately stop the process.

   This ensures that once the power supply returns or is re-established, the process will not start again unchecked.

Steps to take once the power supply has been restored

Procedure

1. Check whether there is still liquid in the vessel.
   - If **YES**: continue with step 2
   - If **NOT**: Restart the CIP/SIP process.
2. Check the pH value to see whether the liquid is still strongly acidic or basic.
3. Start automatic vessel emptying with or without neutralisation – depending on the measured pH value.
   - Restart the CIP/SIP process.
   - Safely stop the process with neutralisation or quickly stop the process without neutralisation using the **Stop CIP/SIP** button.

Steps to take if the power supply cannot be re-established

Procedure

1. Check whether there is still liquid in the vessel.
2. Check the pH value to see whether the liquid is still strongly acidic or basic.
   - If **YES**: see next step
   - If **NO**: continue with step 4.
3. Start fermentation (bioreactor) at a set pH value of 7 and low stirrer speed, about 100 rpm and leave running until the liquid is neutralised.
4. Stop fermentation (bioreactor).

Interferences

5. Remove the hose with the Super Safe Sampler and three-way valve from the harvest pipe.
6. Connect a suitable hose (in-house) to the harvest pipe and lay in the drain.
7. Start fermentation (bioreactor) with the Flow parameter switched on.

   The air flowing in via the air pipe creates excess pressure in the vessel which means that the liquid is pushed out of the vessel through the harvest pipe.

   As soon as the vessel is empty:
8. Stop fermentation (bioreactor).

10.11Returning for Repair

The operator must return the equipment or the faulty component part(s) to the manufacturer if, after consulting the service department of the local dealer or the manufacturer, on-site diagnosis and/or repair is not possible.

The following must be observed if this is the case:

- The equipment or the component part which is to be repaired must be entirely decontaminated before sending to the manufacturer.
- The operator is obliged to firstly fill in and sign a decontamination agreement and decontamination form and either send it together with the written request for the repair work to the licensed dealer before returning the faulty equipment to the manufacturer or, at the latest, together with the faulty equipment on return to the manufacturer.
- These forms can be obtained from the licensed dealer or the manufacturer, contact details can be found on page 2 of this manual.

11 Disassembly

The equipment must be disassembled and disposed of in an environmentally-friendly manner if it is not in use anymore.

11.1 Safety

Personnel

- Disassembly may only be carried out by qualified personnel.
- Qualified electricians only may carry out work on the electrical system.

Inappropriate disassembly

WARNING!
Risk of injury due to inappropriate disassembly!

Residual energy and sharp-edged components of the equipment or tools may cause injuries.

Therefore:

– Before starting the disassembly process, ensure that there is sufficient space for the whole procedure
– Take care regarding sharp-edged components.
– Keep the work place tidy and clean! Discarded components and tools may be a source of accidents.
– Professionally disassemble units: Take note of the high dead weight of some parts. Use hoists, if necessary.
– Secure units to avoid them falling or tumbling down.
– Call the manufacturer in case of any lack of clarity.

Electrical system

DANGER!
Danger of fatal electric shock!

Contact with energised electrical units/components is perilous. Electrical components which are energised may be subject to uncontrolled movements and may lead to most severe injuries.

Therefore:

– Definitely switch and cut off the electrical supply before starting the disassembly-

11.2 Disassembly

Prior to disassembly:

- Switch off the equipment and lock off any isolation switch.
- Physically disconnect the main energy supply from the equipment and wait for any components to fully discharge.
- Remove and dispose of all additional consumable items, auxiliary components and/or spent processing material in an environmental acceptable manner.

Clean and disassemble component parts professionally with regard to any local regulations concerning employment and environmental protection.

11.3 Disposal

Recycle disassembled components, if no agreement is made concerning reclaim or disposal.

- Send metals for scrap
- Send plastic components for recycling
- Sort and dispose of the remaining components according their material composition.

CAUTION!
Environmental damage or loss due to inappropriate disposal!

Electronic waste, electronic components, lubricants or other auxiliary materials/supplies are subject to hazardous waste regulations and may only be disposed of by registered specialist disposal firms

Local authorities or specialist disposal firms can provide information regarding environmentally acceptable disposal.

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