TechCIP
Operating manual
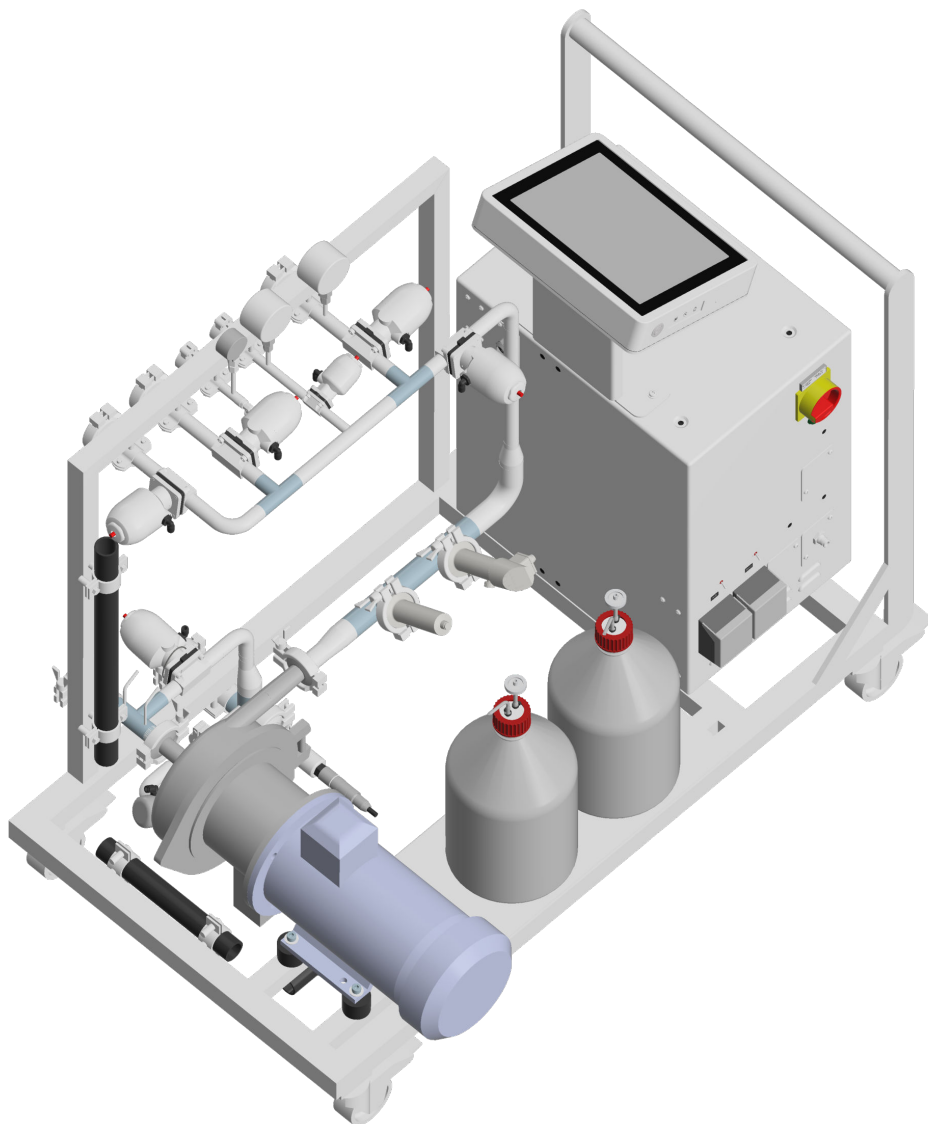
INFORS HT

TechCIP – Rel. 2.0
Mobile CIP Unit
SW: 3.5 / FW: 2.06

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Art. 82311
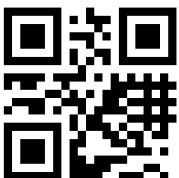
Supplemental Directives

About this Manual

This manual enables the safe and efficient handling of the device. All the information and instructions in this operating manual comply with the current standards, legal regulations and the latest technological developments.

This operating manual is a component part of the device. It must be kept near the device unit and be accessible to staff at all times. All persons working on or with the device must read the operating manual thoroughly and fully understand its contents before beginning any work. Adhering to all the safety notes and operating instructions in this manual is essential to ensure that work is carried out safely.

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

This manual contains illustrations to aid general understanding. These may differ from the actual device as supplied.

Customer Service and Services

Our Customer Service is at your disposal for technical advice and specialist enquiries. For contact information, see page 2. Due to their familiarity with the potential applications of the device, the Customer Service team is able to provide information on whether the unit can be used for a specific application or modified to handle the planned process.

Declaration of Incorporation

The device corresponds to partly completed machinery within the sense of the Machinery Directive 2006/42/EC Article 2.

The device must not be put into service until it has been established that the bioreactor in which the device is to be incorporated complies with the terms of all relevant directives.

The declaration of incorporation as defined in the Machinery Directive, Annex II 1 B is included in the overall documentation of the device.

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1 Safety and Responsibility

This chapter contains general information on safety when using the device. In the remaining chapters, warning messages are used only to highlight particular hazards directly arising from the actions being described.

It is essential to read the operating manual carefully – especially this chapter and the warning messages in the text – and to follow the instructions therein.

This chapter also refers to areas that are the responsibility of the provider due to certain risks arising from particular applications for which the device is used deliberately and with full awareness of the associated risks.

1.1 Explanation of Special Displays

1.1.1 Warning Messages

Warning messages in this manual are indicated by a coloured bar and begin with a signal word that signifies the degree of the hazard.

> ⚠ **WARNING**
>
> The signal word "WARNING" indicates a potentially dangerous situation that may result in severe or fatal injuries if not avoided.

> ⚠ **CAUTION**
>
> The signal word "CAUTION" indicates a potentially dangerous situation that may result in minor injuries if not avoided.

> ❗ **NOTICE**
>
> The word "NOTICE" on a blue bar indicates a situation that may result in significant damage to property if not avoided.

1.1.2 Other Messages

Texts that are marked in this way provide useful tips and recommendations for ensuring efficient, fault-free operation of the device.

Safety and Responsibility

1.2   Intended Use, Incorrect Use and Misuse

Intended Use

> The mobile CIP unit TechCIP has been designed and configured exclusively for cleaning the Techfors-S pilot scale bioreactor of the device manufacturer.

⚠ **WARNING**

The device is designed and built exclusively for the intended use described above.

Each instance of non-conventional use of the device is considered incorrect use and may lead to dangerous situations.

Intended use also includes following all the instructions in this manual, especially those relating to:

- The installation site
- Personnel qualifications
- Correct operation and maintenance
- The use of undamaged tubing and reagent bottles

Incorrect Use/Misuse

Any failure to observe the requirements specified in this manual will be deemed incorrect use.

Any use of the device outside the scope of the intended use as described above will be deemed misuse.

To use the device for special applications not covered by conventional, intended use, the manufacturer must configure and certify the device accordingly.

Any use of the device outside of a biotechnology laboratory, i.e. in any environment in which the conditions required for the safety of personnel cannot be met or cannot be met to their full extent, will also be deemed misuse.

1.3   Qualified Personnel

1.3.1   Operator

The operator operates the device in the context of the intended use. Only persons who have been trained for working in a biotechnology laboratory can be considered for the role of operator. These include, for example:

- Process technicians in the fields of biotechnology and chemistry
- Biotechnologists (biotechnicians)

- Chemists with a specialisation in biochemistry; chemists in the field of organic chemistry or biochemistry
- Life scientists (biologists) with special education in cytology, bacteriology, molecular biology, genetics, etc.
- Lab assistants (lab technicians) from various fields

To be allowed to operate the device, the operator must have received thorough training and have read and understood the operating manual.

The operator must be informed in a training session provided by the provider of the tasks delegated to the operator and the potential risks of improper conduct. Tasks that go beyond the scope of operation under normal conditions may only be performed by the operator if this is specified in the manual and the provider has explicitly entrusted said tasks to the operator.

Persons who are undergoing training or apprenticeships are only permitted to use the device under supervision and in accordance with the instructions of a trained and qualified technician.

1.3.2 Technician

The technician is an individual who, by virtue of their relevant professional education, training and/or experience, is competent to identify risks and prevent hazards arising from the use of the device. The technician is familiar with the environment in which they are operating and knows the relevant standards and regulations.

Technicians include, for example, the following groups of people:

- Qualified electricians
- Decontamination specialists
- Disassembly, disposal and recycling specialists

1.3.3 INFORS HT Service Technician or Licensed Dealer

Certain work may only be performed by the manufacturer's skilled personnel or by skilled personnel authorised by a licensed dealer. Other persons are not authorised to perform this work.

1.4 Unauthorised Persons

The term "unauthorised persons" applies to all persons who can access the work area but are not qualified to use the device in accordance with the aforementioned requirements.

Unauthorised persons are not permitted to operate the device or use it in any other way.

Safety and Responsibility

1.5 Responsibility of the Provider

Provider

The term "provider" applies to all persons who are responsible for making the device and the necessary infrastructure available. The provider bears a special level of responsibility with regard to the processes and the qualification and safety of the operators.

Provider Obligations

The device is used for industrial and scientific purposes. As such, the provider of the device is individually liable with regard to the legal requirements relating to occupational health and safety in a biotechnology laboratory. In particular:

- The provider is responsible for ensuring that the work and environmental regulations applicable in a biotechnology laboratory are observed.
- The provider must ensure that the device remains in safe and proper working condition throughout its entire term of use.
- The provider must ensure that all safety devices are fully functional and not disabled.
- The provider must ensure that the device is only operated by qualified personnel, and that said personnel receive sufficient training.
- The provider must ensure that the protective equipment required for working with the device is available and worn.
- The provider must ensure that this operating manual remains in the immediate vicinity of the device throughout its entire term of use.

1.6 General Hazards

This chapter covers general hazards and residual risks that are always present when using the device in accordance with normal, intended use.

The following notices are general in nature. As such, with a few exceptions they are not repeated in the remaining chapters.

Electric Current

The device is operated electrically. There is an immediate risk of fatal injury if contact is made with live parts. The following points must be observed in order to avoid the risk of fatal injury:

- In case of damage to insulation, disconnect the device from the power supply immediately and arrange for it to be repaired.
- Disconnect the device from the power supply before commencing any work on the electrical components.
- Always use qualified electricians for any work on the electrical components.
- Keep moisture away from live parts. It could cause a short circuit.

Accessories and Spare Parts

Incorrect spare parts, imitations or spare parts that have not been authorised by the manufacturer and unauthorised accessories represent a significant safety risk. As such, we recommend procuring all spare parts and accessories from a licensed dealer or directly from the manufacturer.

1.7   Particular Hazards

This chapter covers particular hazards and residual risks that may arise when using the device for special applications in accordance with normal, intended use.

Since the use of the device for such applications is deliberate, it is the responsibility of the operators and the provider to ensure that all personnel are protected from potential damage to health. The provider is responsible for ensuring that the appropriate protective device for such applications is provided, and that the necessary infrastructure is in place.

Hot Surfaces

For processes that are performed with temperatures over 55 °C, there is a risk of burns on hot surfaces.

Since the device is intended for applications at high temperatures, it is the personnel's responsibility to ensure that they have sufficient protection.

Corrosive, Caustic Substances
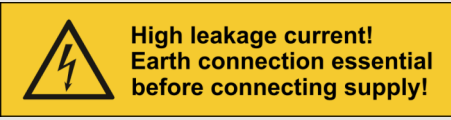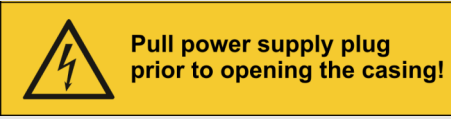
The use of corrosive or caustic substances entails a significant health risk. As such, special measures must be taken to protect personnel in these cases.

Since cleaning cycles with acid and base are envisaged for the CIP process, such materials are used deliberately. Personnel is responsible for ensuring adequate protection.

1.8   Warning Symbols on the Device

The following warning symbols (stickers) are placed on the device:

Safety and Responsibility

Warning symbol	Position	Meaning
High leakage current! Earth connection essential before connecting supply!	On the instrumentation cabinet	Danger due to high leakage current. Before connecting to the supply circuit, a ground connection must be established.
Pull power supply plug prior to opening the casing!	On the instrumentation cabinet	Danger due to electrical voltage. Turn off the device and pull out the power plug before opening the housing of the device.

⚠ **WARNING**

Illegible or missing warning symbols on the device will lead to the personnel being exposed to risks that the warning symbols in question were designed to make them aware of.

It is the provider's responsibility to ensure that all the stickers with warning symbols on the device are always intact.

1.9   Declaration of Decontamination

When returning the device for repair, disassembly or disposal, a legally compliant declaration of decontamination is required for the safety of all involved and due to legal requirements. The following must be observed if this is the case:

- The device, component or accessory which is to be repaired must be entirely decontaminated before being sent to the manufacturer.
- The provider is therefore required to completely and truthfully fill out a declaration of decontamination, and have it signed by the person responsible.
- The declaration of decontamination must be affixed on the outer packaging in which the device is sent back.
- These forms can be obtained from the licensed dealer or the manufacturer. See address on page 2.

ⓘ If the return shipment is not accompanied by a signed and complete declaration of decontamination or it is not affixed to the outer packaging, the shipment will be returned unopened to the sender at their expense (see also T&C).

2 Setup and Function

2.1 Overview of the Device

Overall Device
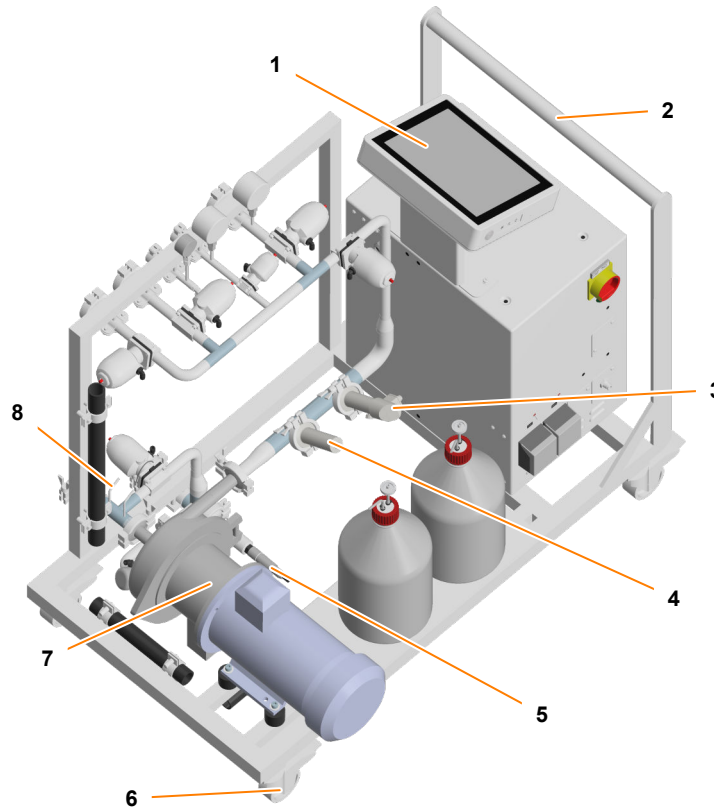
1	Operating panel	5	Conductivity sensor *16.37.01*
2	Rolling frame handle	6	Swivel castor
3	Pressure sensor *16.31.01*	7	CIP pump *16.22.03*
4	Water sensor *16.38.01*	8	Addition port adapter

The mobile CIP unit TechCIP is designed for cleaning the Techfors-S pilot scale bioreactor. It is mounted on a rolling frame with four swivel castors and a handle for pushing or pulling. The swivel castors have brakes that can be locked. The side of the frame features a storage area for the reagent bottles.

Setup and Function

Cleaning Process	The cleaning process (CIP process) is configured and started via the operating panel mounted on the instrumentation cabinet, and runs automatically. Process water and air (pressurised air) for the various cleaning and rinsing cycles are controlled using pneumatic diaphragm valves.

The CIP pump ensures liquid is circulated during the rinsing cycles. The water sensor detects the liquid level in the circuit during the entire CIP process. The pressure sensor monitors the pressure sensor in the circuit while the CIP pump is active. The conductivity sensor measures the conductivity of the waste water during the final rinse.

During the process, the vessel of the bioreactor acts as the receiver tank for the cleaning solution. Two CIP lances with spray balls clean the surfaces of the vessel in contact with medium. Base and acid are added from the reagent bottles via the two pumps on the instrumentation cabinet and two addition port adapters in the piping.

Cleaning Media

The type and degree of contamination of the bioreactor depend on the cultivation carried out previously. The base and, if necessary, acid to be used, their concentration and the cleaning temperatures and times compatible with them are defined and, if necessary, validated by the user. Caustic soda or potassium hydroxide, for example, are frequently used. If acid is used, then for example, citric acid or phosphoric acid are used.

2.2   Identification Plate

Position

The identification plate for identifying the device is located on the instrumentation cabinet and next to the connections for water, air, etc.

Content

The identification plate is designed to allow clear identification of the device. It contains the following information:
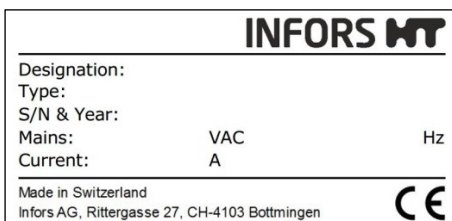
- Manufacturer's name
- Designation = category of device
- Type = device type (name)
- S/N = serial number
- Year = year of manufacture
- Mains = nominal voltage and frequency
- Current = power consumption
- Manufacturer's address
- CE marking

2.3 Operating and Display Elements

2.3.1 Main Switch
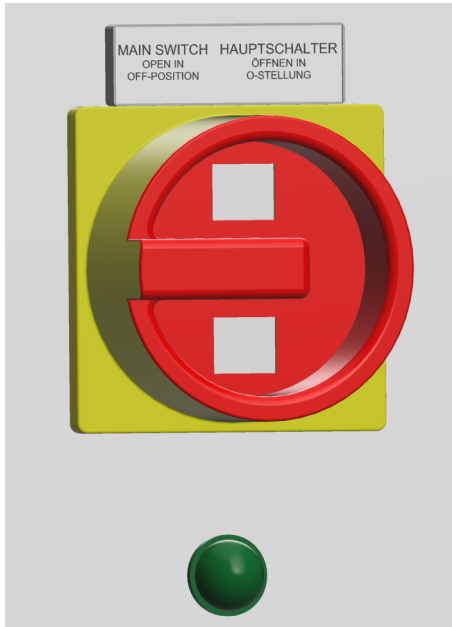
The main switch is located on the top right-hand corner on the front of the instrumentation cabinet.

- To switch on the device, turn the main switch clockwise (90 degrees) into position *I/ON*.

  The green power indicator light underneath the main switch lights up. The device is switched on and in idle state.

- To switch on the device, turn the main switch counter-clockwise (90 degrees) into position *0/OFF*.

  The green power indicator light switches off. The device is cut off from the power supply. Only the main power supply terminal is powered.

If necessary, for maintenance purposes, secure the main switch against being switched on again by attaching a lock (not included in the scope of delivery) and also disconnect the power plug.

> **❗ NOTICE**
>
> Switching off via the main switch without first stopping the running process and/or shutting down the system at the operating panel can result in damage to the operating panel!

2.3.2 Operating Panel

The operating panel is attached to a holder mounted on the top of the instrumentation cabinet. It has a 12" colour touch screen with protection type IP66. The operating panel is switched on using the main switch.

Setup and Function

Monitor Buttons on the Operating Panel
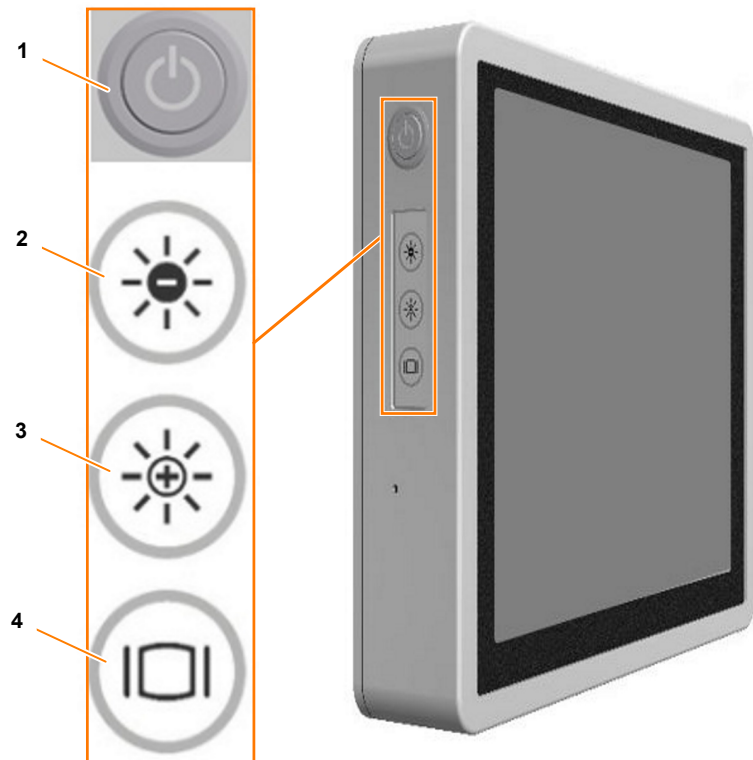
1 **ON/OFF** key
2 **DARK** key: setting the screen illumination to darker
3 **LIGHT** key: setting the screen illumination to brighter
4 **DISPLAY** key: switching the screen on or off

The **ON/OFF** key lights up when the operating panel is switched on. Since switching on/off takes place via the main switch, there is no need for separate switching on/off via the **ON/OFF** key. Switching off via the **ON/OFF** key while a process is running has the same effect as a power failure.

Operating Panel Connections
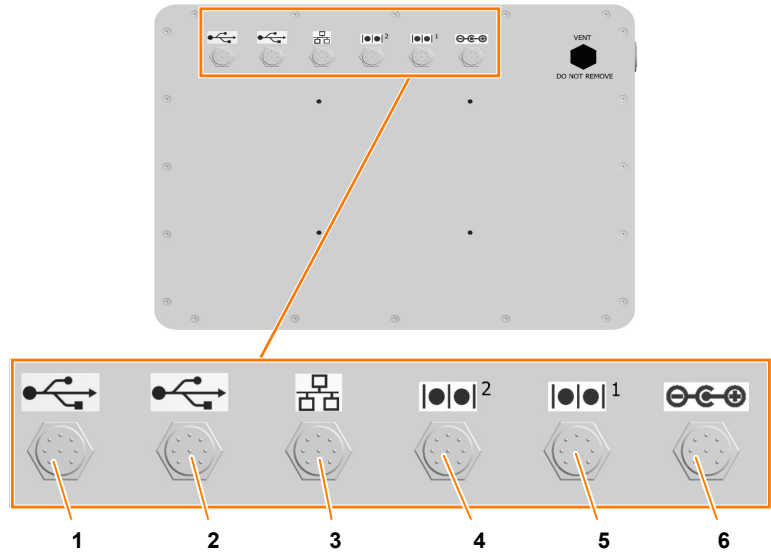
1   USB2.0 x 2: for backups and service purposes [1]
2   USB2.0 x 2: reserve
3   Ethernet: for connecting to a network [1]
4   COM2: reserve
5   COM1: connection for iDDC-Bus cable [1] (display cable), connection is additionally marked with *RS485*
6   DC: connection for power supply cable [1]

[1] *Cable included in scope of delivery.*

Setup and Function

2.4 Pumps

Function
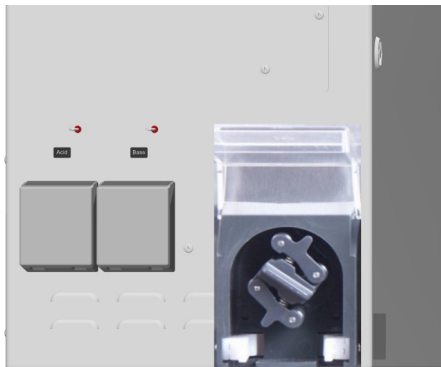
The two digital peristaltic pumps *Acid* and *Base* with a hinged cover are positioned at the lower part of the instrumentation cabinet. The pumps are driven by stepper motors and run clockwise in automatic operation. Automatic pump operation is integrated into the various CIP sequences of the touch screen software. Depending on the various rinsing cycles, either the base or acid pump is automatically activated during the ongoing CIP process.

Operation
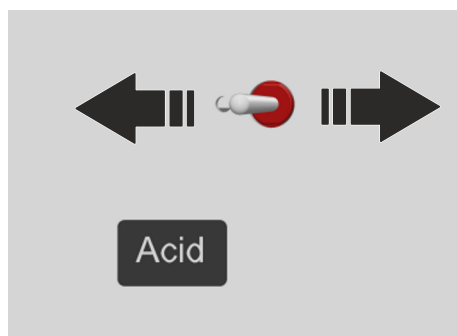
The pumps can also be operated manually via the rocker switches located above the pump heads when the device is switched on:

- Flick the rocker switch to the right: the pump runs clockwise.
- Flick the rocker switch to the left: the pump runs counter-clockwise.

2.5 Air Bleed Valve

The air bleed valve *16.06.01*, a solenoid valve, has two functions:

- It is used to prevent excess pressure in the vessel of the pilot scale bioreactor Techfors-S.
- It protects the vessel of the pilot scale bioreactor Techfors-S and the CIP cycle from a vacuum while the CIP pump is active.

The air bleed valve is hardwired to the control board in the TechCIP instrumentation cabinet and is controlled by the running CIP process. It is closed when not switched on.
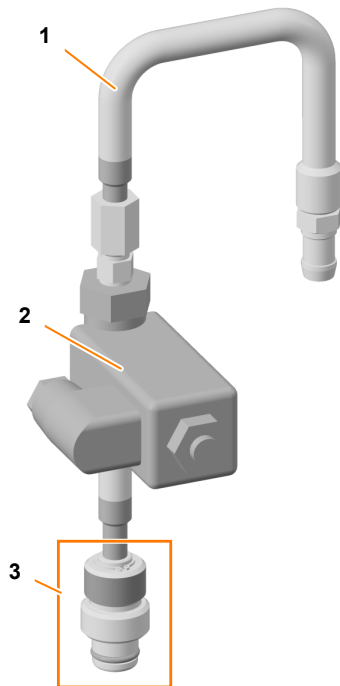
1   Elbow
2   Solenoid valve
3   Clamping adapter with fixed O-ring

During the entire CIP process, the air bleed valve must be mounted in one of the 19 mm ports in the vessel top plate of the Techfors-S pilot scale bioreactor that is to be cleaned. The air bleed valve has an elbow and a clamping adapter with a fixed O-ring for mounting.

While the CIP process is running, liquid comes out of the elbow. To discharge it safely, the scope of delivery includes a suitable pressure hose (diameter 6 x 11.9 mm) with the hose clamp. The hose must be attached to the elbow and installed in the same non-pressurised drain as the hose line for the wastewater.

2.6   CIP Lances and Hose Lines

The connection between the mobile CIP unit and the Techfors-S pilot scale bioreactor uses various hose lines.

Hose Pair with CIP Lances
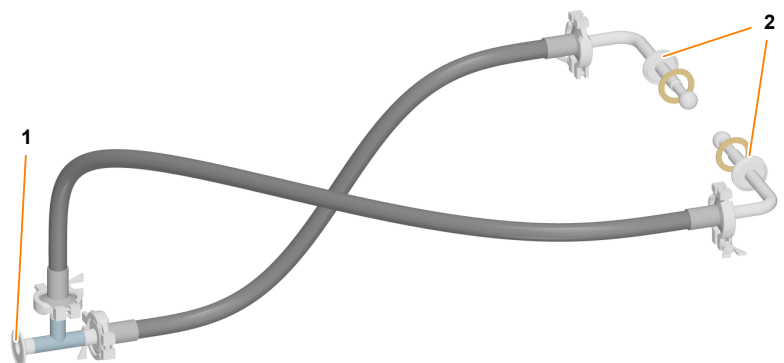
1   CIP unit connection: *CIP out*
2   Bioreactor connection: *CIP lance 1 + 2* (vessel collar)

The CIP lances and hose ends have Tri-Clamp connections. The hose pair is connected to the CIP unit via a tee.

Setup and Function

Hose Pair Inlet Air and Exit Gas
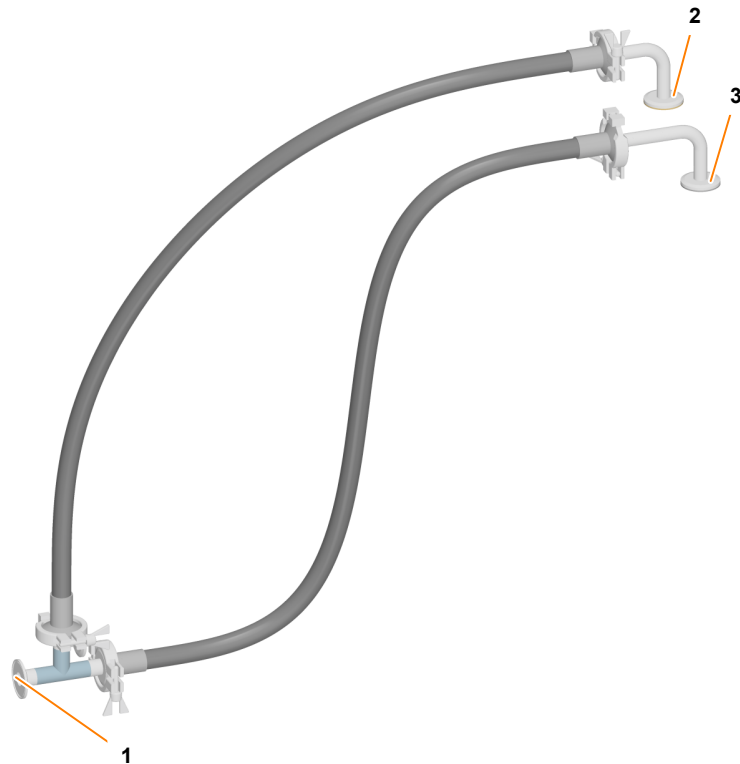
1   CIP unit connection: *CIP periphery*
2   Bioreactor connection: *CIP periphery 1* (exit gas)
3   Bioreactor connection: *CIP periphery 2* (inlet air)

The hose pair has Tri-Clamp connections on both ends and is con-
nected to the CIP unit via a tee.

Hose for Harvest/Sample Valve

1   CIP unit connection: *CIP in*
2   Bioreactor connection: *CIP out* (harvest/sample valve *05.12.01*)

The hose line has Tri-Clamp connections on both sides and a bend
with nozzle and groove nut for connection to the bioreactor's harvest/
sample valve.

3   Accessories

3.1   Reagent Bottles

3.1.1   Setup and Function

Two reagent bottle bottles are supplied equipped with hoses and filters for adding acid and base.
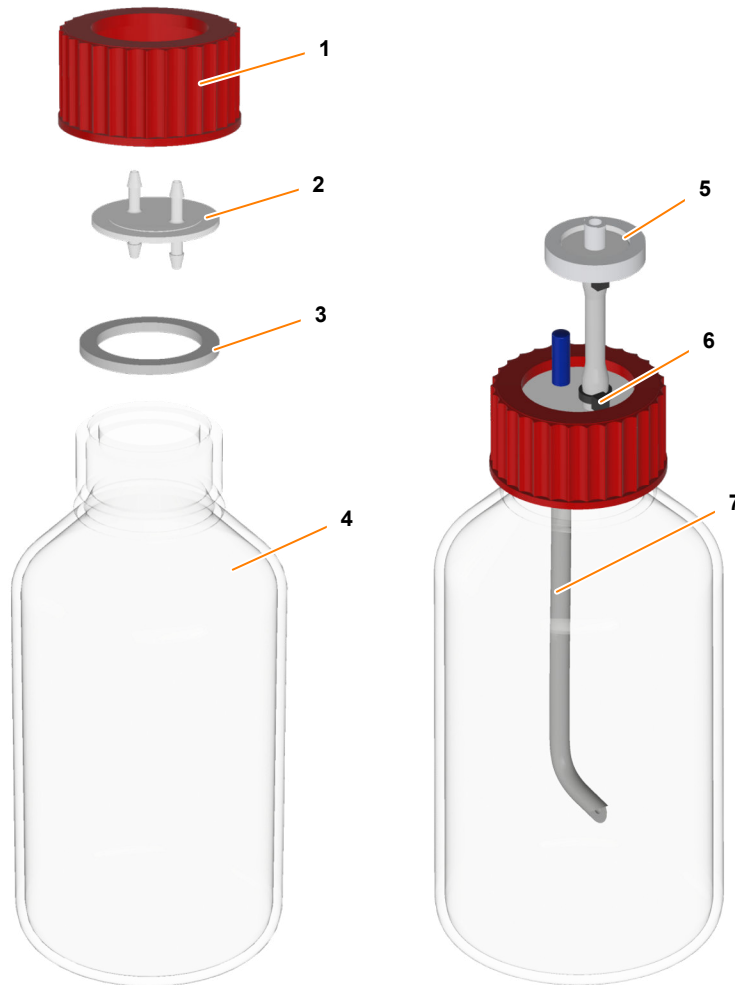
1 Screw cap	5 Filter
2 Hose connector plate	6 Cable tie
3 Flat gasket	7 Silicone hose
4 Laboratory bottle	

Accessories

3.1.2 Equipping the Reagent Bottles

> ℹ️ Suitable pump hoses are not included in the scope of delivery and either have to be ordered separately or otherwise provided by the provider.

> ❗ **NOTICE**
>
> Damaged hoses and/or clogged filters can lead to undesirable pressure ratios in the reagent bottles.
>
> – Equip each reagent bottle with an open pressure equalisation line and a clean and dry filter.
> – Use only clean and intact hoses and affix these properly.

To equip an unloaded reagent bottle for use, proceed as follows:

1. Unscrew the screw cap together with the hose connector plate.

2. Fit a piece of silicone hose onto one of the two hose connectors on the inside of the plate.

   Choose the length so that the hose end does not touch the bottom of the bottle. Otherwise, the hose may get sucked against the bottom and no longer be able to pump liquid.

   > ℹ️ Alternatively, the hose end can be cut at an angle. In this case, the hose end can touch the bottom of the bottle.

3. Secure all hose connections with cable ties.

4. Place a long piece of silicone hose on the equilateral connection on the outside of the hose connector plate.

   Choose the length of the hose so that it reaches from the reagent bottle to the pump on the instrumentation cabinet without tension or sharp kinks.

5. Place a short piece of silicone hose on the second connection on the outside of the hose connector plate.

6. Fit the filter on the short hose piece.

7. ▸ Secure the hose connections with cable ties.

> **ⓘ NOTICE**
>
> Use of highly corrosive cleaning media, such as hydrochloric acid HCl, can cause damage to components that come into contact with it.

8. ▸ Fill the reagent bottle and close it with the screw cap.

9. ▸ Ensure the flat gasket between bottle neck and top plate sits and seals correctly.

10. ▸ Clearly label the reagent bottle according to its content.

11. ▸ Connect a suitable piece of pump hose (Marprene/Bioprene recommended) to the silicone hose of the reagent bottle using a hose connector.

12. ▸ Connect a fitting piece of silicone hose with a hose connector to the open end of the pump hose.

13. ▸ Secure all hose connections with cable ties.

3.1.3   Connecting the Reagent Bottles

Connecting the Silicon Hoses

To connect the reagent bottles to the mobile CIP unit, proceed as follows:

1. ▸ Place the reagent bottles on the storage surface of the mobile CIP unit.

2. ▸ Place the silicone hoses of the reagent bottles on an addition port adapter and secure with cable ties.
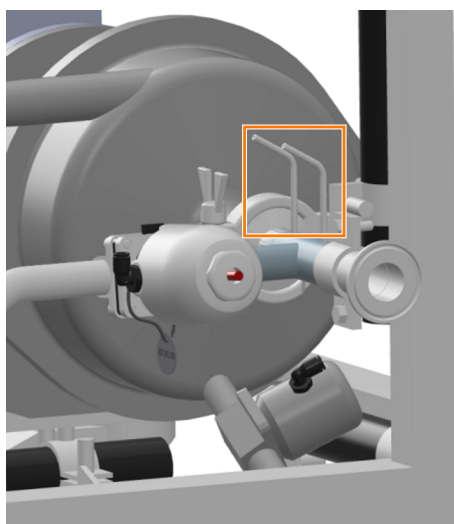
> ⓘ If only one reagent is used for the CIP process, that is, one addition port adapter remains unused; make sure you seal it. To do so, attach a piece of hose and clamp it well.

> **⚠ WARNING**
>
> Hot and/or corrosive liquid can cause severe burns, scalds or chemical burns!

Inserting the Pump Hoses

To insert the pump heads, proceed as follows:

Accessories

1. ▶ Lift up the pump cover on the instrumentation cabinet.

2. ▶ Press the left white clamp against the inside and at the same time insert the pump hose according to the direction of pump rotation (clockwise).

3. ▶ Release the clamp.

   ➡ The pump hose is now secured by the left clamp.
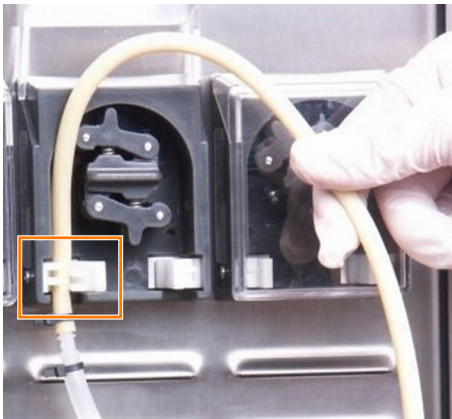
4. ▶ Thread the pump hose around the pump head and push in gently.

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

> ⚠️ **CAUTION**
>
> Danger of pinching fingers!
>
> If the pump is operated electrically (rocker switch) when the pump hose is inserted, this can lead to pinched fingers and damage to the pump hose.
>
> Always turn the pump head by hand when inserting the pump hose.

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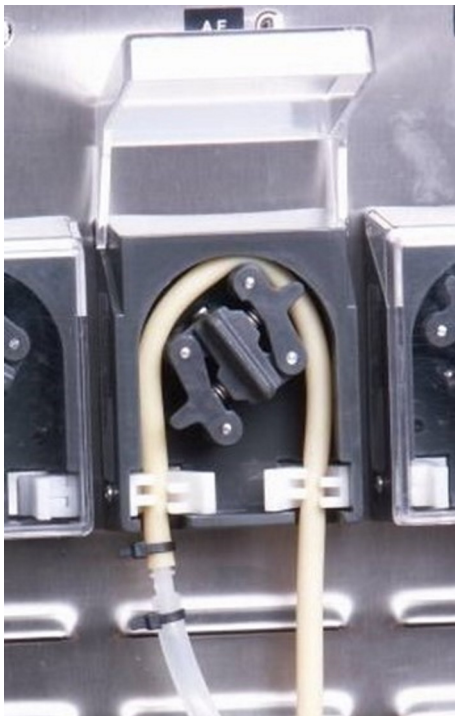
7. ▸ Release the clamp.

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

8. ▸ Fold down the pump cover.

9. ▸ Fill the hoses manually or via the touch screen software.

Accessories

3.1.4 Specifications

Volumes/hoses

Data	Value	Unit
Volume	5000	ml
Silicone hose diameter	3 x 5	mm
Silicone hose length	3.4	m

Filter

Data	Value	Unit
Filter diameter (hydrophobe)	25	mm
Filter retention rate	0.45	µm

Materials

Data	Value
Laboratory bottle	Borosilicate
Flat gasket	Silicone
Filter membrane	PTFE
Hose connector plate	PDVE

4   Transport and Storage

The following specifications are based on transport and storage of an unpacked device at the provider's site.

4.1   Transport

Due to the mobile CIP unit's rolling frame, it is usually easy to transport. If the mobile CIP unit has to be lifted for internal reasons, ensure that the components under the frame are not damaged.

4.2   Storage

- Decontaminate, thoroughly clean and dry the device every time before placing it in storage.
- Maintain and store sensors produced by other manufacturers in accordance with their instructions.
- Store the device and its components clean, dry and protected against dust, dirt and liquids.
- Store the device and its components in a cool place with low humidity but protected against frost.
    - Storage temperature: 5 °C to 55 °C.
    - Relative humidity, non-condensing: 10 % to 95 %.
- Protect the device from aggressive media, direct sunlight and vibrations.

5 Connection and Preparation

This chapter describes which connection requirements the provider must meet on the building side as well as general connection requirements. This chapter also describes how to establish the connection from the mobile CIP unit to the Techfors-S pilot scale bioreactor to be cleaned.

5.1 Operating Conditions at the Installation Location

The following requirements must be met at the installation location of the mobile CIP unit.

- The figures and ranges specified in ➡ Chapter 10.2 'Connections and Connection Values' on page 101 and ➡ Chapter 10.4 'Operating Conditions' on page 105 must be observed.
- The mobile CIP unit must only be installed inside a laboratory or a laboratory-like environment.
- The installation site must be level, sufficiently stable and able to bear loads.
- There must not be any sources of electrical interference near the unit.

5.2 Minimum Distances to the Device

To operate and maintain the mobile CIP unit it must be installed with a minimum distance of 50 mm from walls, ceilings or other equipment. The maximum distance between the mobile CIP unit and the bioreactor to be cleaned is predefined by the length of the connecting hoses.

5.3 Requirements for the Mains Connection

To avoid dangers due to electrical current, the in-house mains connection must meet the following requirements:

- Single-phase, constant power supply
- In the building, the power supply must be protected using a fault current protection switch (RCD – Residual Current Device).

> ⚠ **WARNING**
>
> Danger due to high leakage current.
>
> Prior to connecting the power supply circuit, the earthing connection must be established!

In addition to that, ensure the following:

- Make sure that the voltage values of the device match those of the local mains voltage. Note the description on the identification plate.
- Only use the power cable provided. If the power cable becomes defective, replace it with a power cable of the same type.
- Ensure that the mains connection is accessible at all times.

Refer to the technical data for the electric connection values, see ➡ 'Electrical Connection Values' on page 102.

5.4 Water

Water conditions for the process:

- Quality: Water for injection (WFI)
- Constant supply at a pressure of 2.0 ± 0.2 bar

5.5 Waste Water

Waste water/drainage conditions:

- The waste water drain must be heat resistant (max. 80 °C) and free of counter pressure.
- The drain must not be in the immediate vicinity of the operator.

> ⚠ **CAUTION**
>
> Hot water may come out of the waste water outlet.

Connection and Preparation

■ Waste water must be safely discharged and disposed of or recycled in an environmentally sound manner.

> ⚠ **WARNING**
>
> Health risk and environmental hazard due to contaminated waste water!

5.6 Air

Pressurised air conditions for the CIP process:

■ Constant supply at a pressure of 2.0 ± 0.2 bar

■ Air is dry, clean, and free of oil and dust

■ Recommended compressed air quality as per DIN ISO 8573-1: Class 1,2,3,4

> ❗ **NOTICE**
>
> Using compressed air containing water or oil or contaminated air can damage the pilot and/or process valves!

5.7 Instrument Air

Pressurised air conditions for pilot valves:

■ Constant supply at a pressure of 6.0 to 7.0 bar

■ Pressurised air is dry, clean and free of oil and dust (recommended pre-filter: 10 μm)

> ❗ **NOTICE**
>
> Using compressed air containing water or oil or contaminated air can damage the pilot and/or process valves!

5.8 Hoses

Conditions for all hoses used:

■ Use pressure-resistant and intact hoses.

■ Use hoses with an appropriate diameter; an adapter may be used, if necessary.

■ Secure hoses using appropriate hose clamps.

5.9   Preparing the Reagent Bottles

The reagent bottles adding acid and base must be equipped for use and connected to the mobile CIP unit before the cleaning process starts. The pump hoses are then filled. This work is described in detail in ➡ Chapter 3.1.2 'Equipping the Reagent Bottles' on page 24, ➡ Chapter 3.1.3 'Connecting the Reagent Bottles' on page 25 and ➡ Chapter 6.4.1 'Filling and Emptying the Pump Hoses' on page 77.

5.10   Connecting the Mobile CIP Unit to the Bioreactor

To operate the mobile CIP unit with the Techfors-S pilot scale bioreactor, the following components must be connected:

- Hose pair for inlet air and exit gas
- Hose pair with CIP lances
- Hose line to the harvest/sample valve *05.12.01*
- Air bleed valve *16.06.01*

Before starting any work, make sure that the swivel castors of the mobile CIP unit and the bioreactor are locked.

5.10.1 Connecting the Hose Pair for Inlet Air and Exit Gas
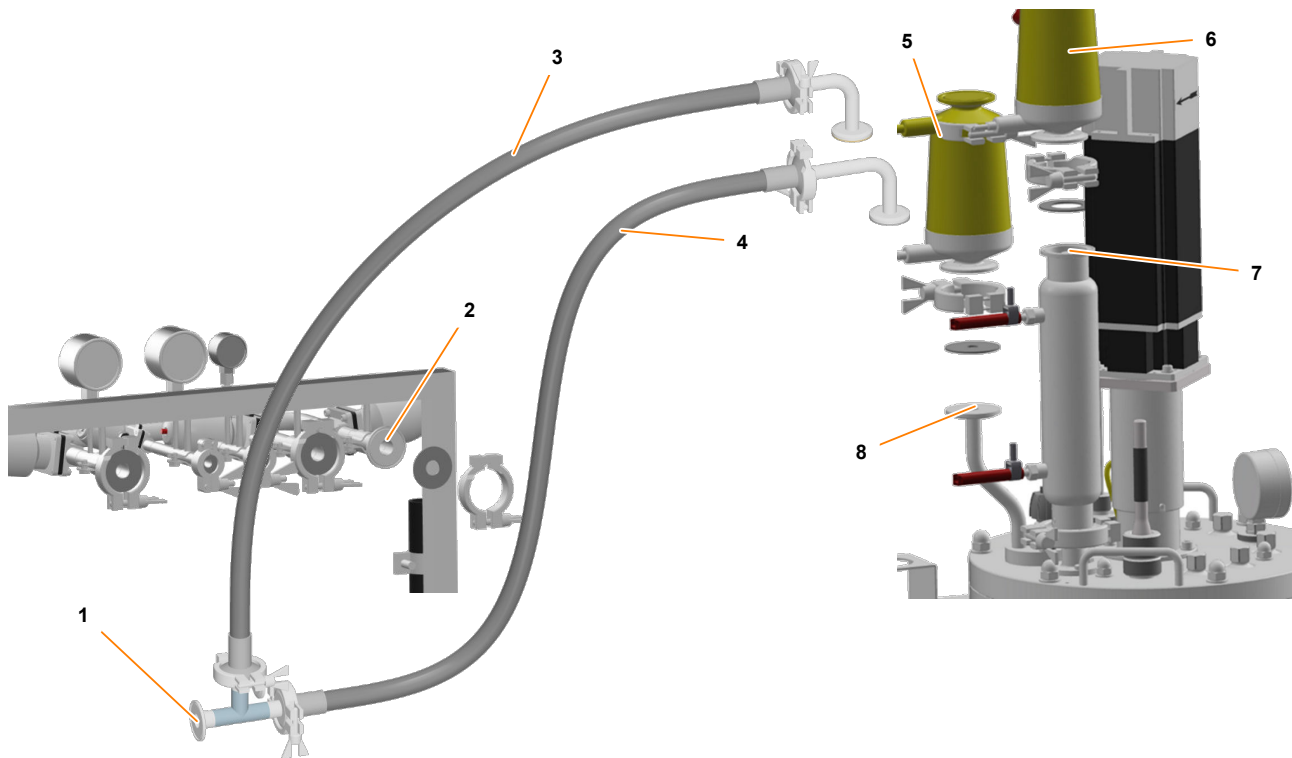
To connect the hose lines for inlet air and exit gas, proceed as follows:

1. Connect the tee (1) of the hose pair equipped with the flat gasket with a clamp to the *CIP periphery* (2) connection of the mobile CIP unit.

2. Remove the filters for inlet air (process gas) (5) and exit gas (6) from the bioreactor.

3. Connect the CIP hose for exit gas (3) with a clamp and flat gasket from the exit gas filter to the exit gas cooler (7).

4. Connect the CIP hose for inlet air (4) with a clamp and flat gasket from the inlet air filter to the connection for inlet air (process gas) (8).

5. Check and make sure that the hoses are tight and have no kinks.

5.10.2   Connecting the Hose Pair with CIP Lances
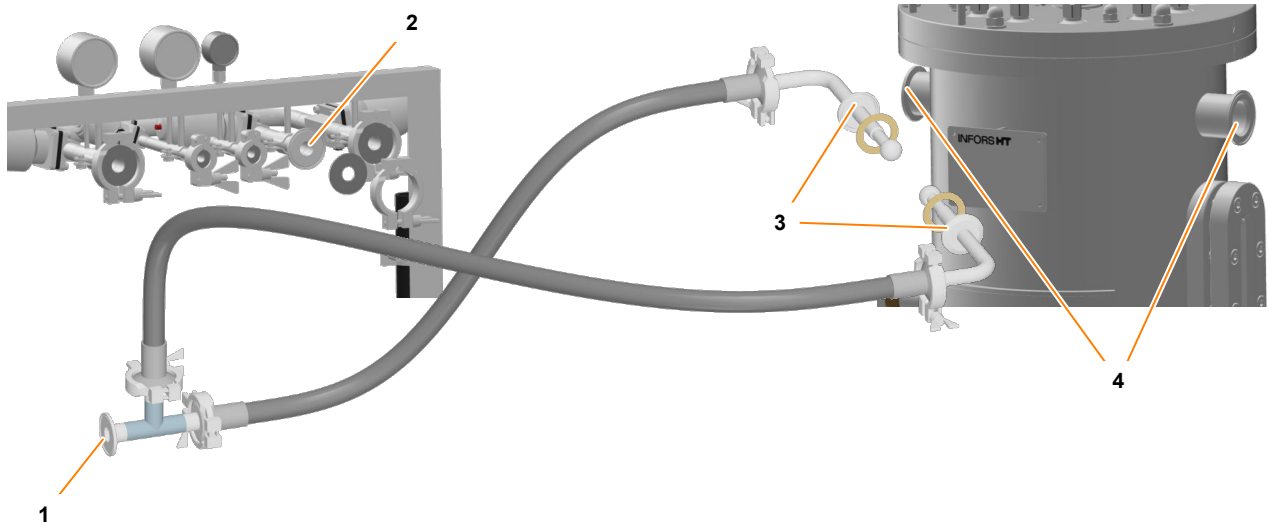
To connect the hose lines with the CIP lances, proceed as follows:

1. ▸ Connect the tee (1) of the hose pair with the flat gasket and clamp to the *CIP out* (2) connection of the mobile CIP unit.

2. ▸ Remove both blanking plugs (not depicted here) of the lateral Tri-Clamp ports (4) on the vessel collar of the bioreactor.

3. ▸ Insert the CIP lances (3) equipped with flat gaskets and affix them with the clamps of the blanking plugs.

4. ▸ Check and make sure that the hoses are tight and have no kinks.

Connection and Preparation

5.10.3 Connecting the Hose to the Harvest/Sample Valve
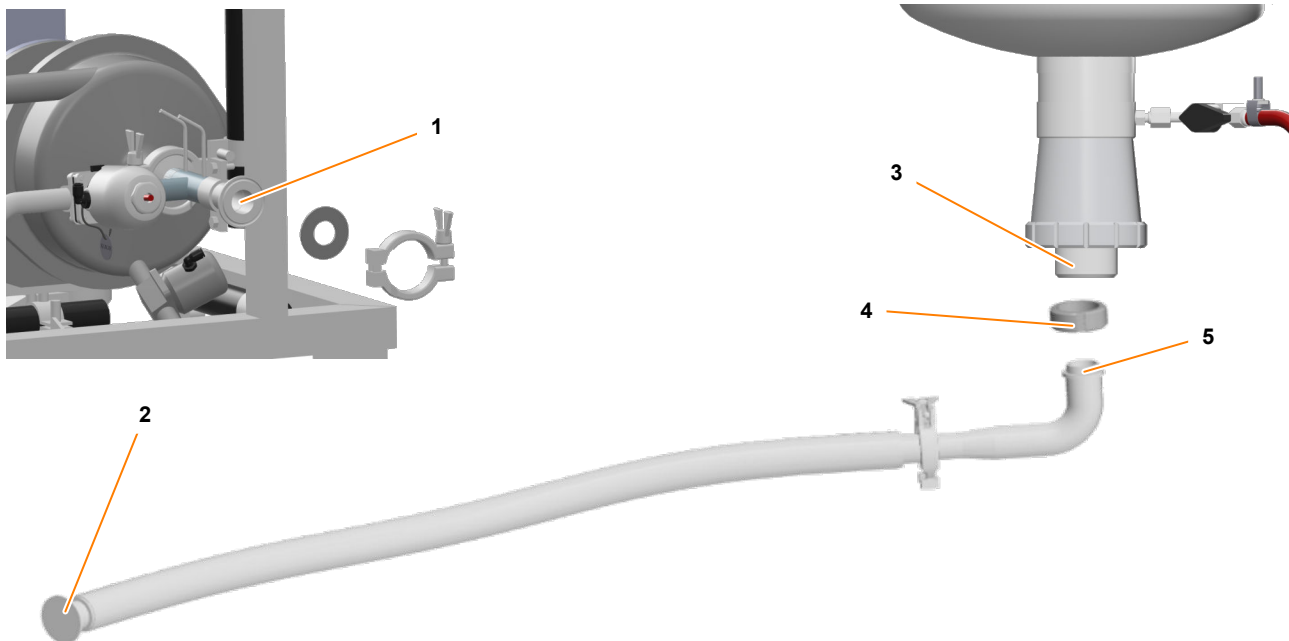
To establish the hose connection between the mobile CIP unit and the bottom valve (harvest/sample valve *05.12.01*) of the bioreactor, proceed as follows:

1. ▸ Connect the CIP hose end (2) with the flat gasket and clamp to the *CIP In* connection (1) of the mobile CIP unit.

2. ▸ Loosen the groove nut (4) on the harvest/sample valve *05.12.01* of the bioreactor and, if appropriate, remove the valve insert with the needle (not pictured).

3. ▸ Screw the CIP hose end with pipe elbow (5) to the valve cylinder (3) using the groove nut (4).

4. ▸ Check and make sure that the hose is tight and has no kinks.

5.10.4 Preparing the Air Bleed Valve

For the CIP process, the air bleed valve must be mounted in the vessel top plate of the Techfors-S bioreactor.

Since liquid can escape from the elbow of the vent valve during the CIP process, the supplied pressure hose must be connected and routed to the waste water drain.

> ⚠ **WARNING**
>
> Hot and/or corrosive liquid can cause severe burns, scalds or chemical burns!

Mounting the Air Bleed Valve
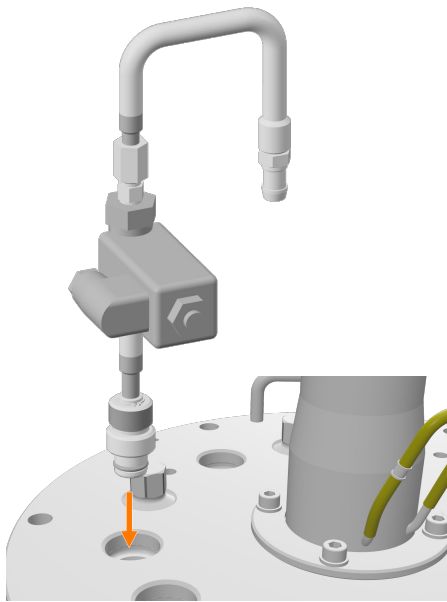
1. ▸ Insert the air bleed valve with fixed O-ring into the 19 mm port in the vessel top plate of the Techfors-S pilot scale bioreactor.

2. ▸ Manually tighten the air bleed valve.

Connecting the Pressure Hose
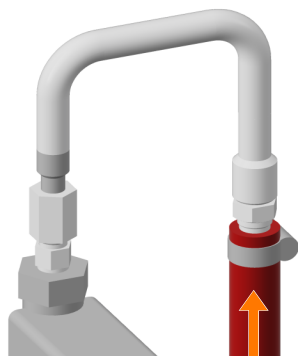
1. ▸ Connect the supplied pressure hose to the end of the pipe elbow on the air bleed valve and secure it with a hose clamp.

2. ▸ Route the open end of the pressure hose into the waste water drain that is free of back pressure.

6 Operation

This chapter describes all touch screen software functions accessible to the operator in detail. It also describes the emergency off and restarting after a shutdown.

> ! **NOTICE**
>
> Changes to settings in the touch screen software by unqualified or untrained personnel can lead to malfunctions.

Most of the illustrations of the various menus, dialogue boxes and tab pages of the touch screen software in this manual correspond to the view of a user of the *Technicians* user group and serve as examples. For more information on user groups and access rights, see → Chapter 6.3.2.2 'User Groups' on page 55 and chapter → Chapter 6.3.2.3 'Access Rights' on page 56

6.1 Overview Screen, Menu Navigation and Control Elements
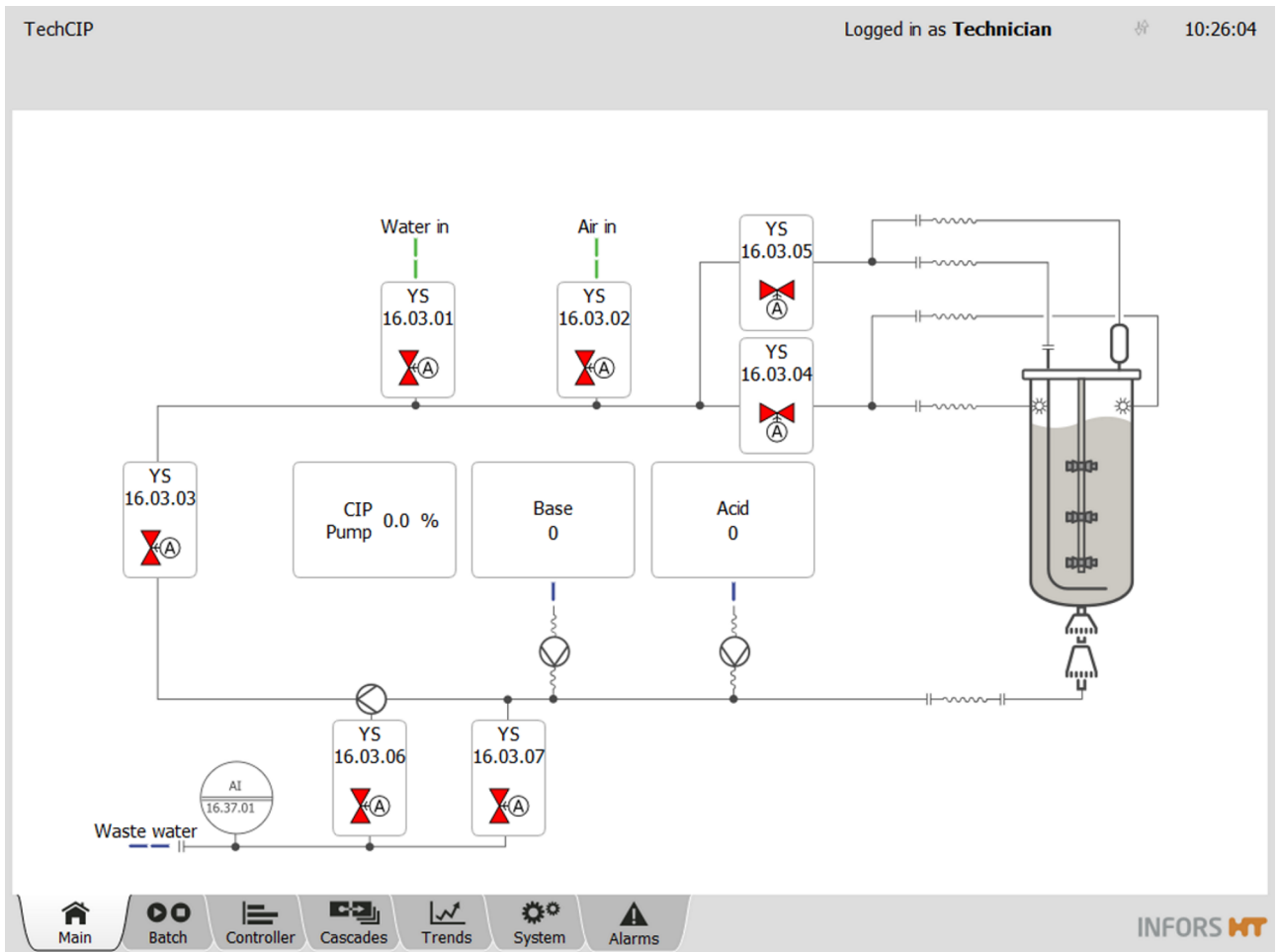
Sections

Title bar	Shows the device name, operating states, warning messages, login status and time. If an external software like eve® accesses the OPC XML DA server of the touch screen software, this is indicated by two vertically opposed arrows in the title bar. These flash while data is being transmitted.
Main section	Shows the main menus and submenus. Inputs are only made in the main section.
Footer	The footer consists of 7 tabs that provide access to the 7 main menus. The tab of a selected main menu is displayed with a light grey background.

Operation

Main Menus

The following main menus are available (from left to right):

- *Main*: Graphically displays the mobile CIP unit with pumps and valves as well as the connection to the bioreactor.
- *Batch*: This is where the CIP process is started and stopped, and where the peristaltic pumps are calibrated.
- *Controller*: Shows the measured value of the conductivity sensor and whether the CIP pump and the two peristaltic pumps for acid and base (*Acid* and *Base*) are switched on or off.
- *Cascade*: Allows serial, parallel or parallel serial (mixed) cascaded control of one or more parameters.

> ⓘ This menu is not relevant for the mobile CIP unit.

- *Trends*: Shows trend lines of the conductivity measurement as well as the activity of the CIP pump and the two peristaltic pumps, time spread between 15 min and 2 days.
- *System*: Provides access to the submenus *Valves*, *Security*, *Settings*, *Wipe Screen* and *Shutdown*.
- *Alarms*: Shows user and system alarms.

Buttons

| Start | Stop |

Different buttons are displayed depending on the selected main menu or submenu and access rights. Pressing buttons opens submenus, dialogue boxes or tab pages. Available buttons have a white background, buttons that are not available appear grey.

Buttons that are intended to be the next logical step are highlighted in orange colour, see figure in next section.

Dialogue Boxes and Tab Pages

A dialogue box can contain instructions, notes, warnings and general information.

> **Confirmation**
>
> Do you want to shutdown system?
>
> | Cancel | OK |
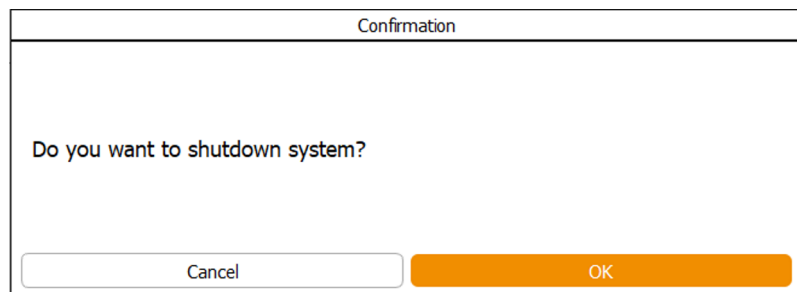
A dialogue box can contain additional buttons, input fields or view boxes as well as tab pages. For example, dialogue box *CIP Operation: configuration* with tab pages that lead to the configuration menus of the various process phases.
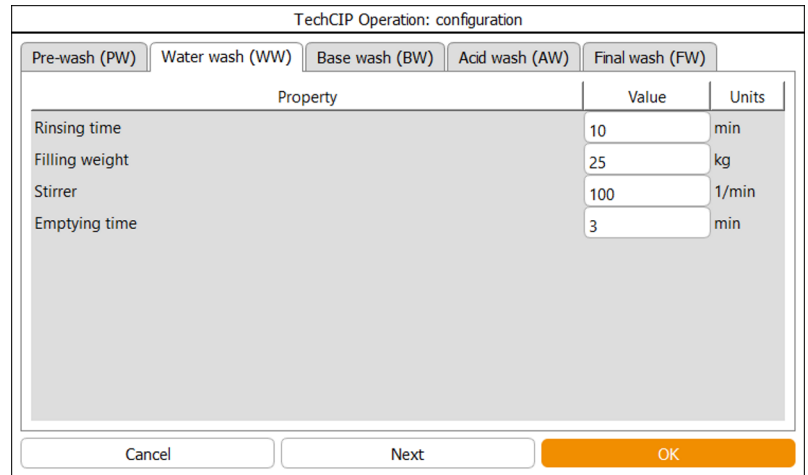
Input Fields and View Boxes

Input fields and view boxes are included in various menus, dialogue boxes and tab pages. They require numeric or alphanumeric values to be entered or display these.

Numeric Keypad and Alphanumeric Keyboard

Numeric values are entered using a numeric keypad and alphanumeric values are entered using an alphanumeric keyboard. After pressing an input field, the corresponding block for the input appears, depending on the type of field.
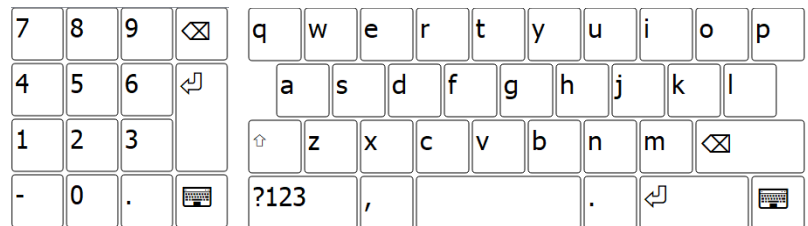
ON/OFF Switch

The **ON/OFF** switch is used for activating or deactivating a function.

ON: The switch is orange.

OFF: The switch is white.

Operation

6.2 Main Menus

6.2.1 Main – Overview
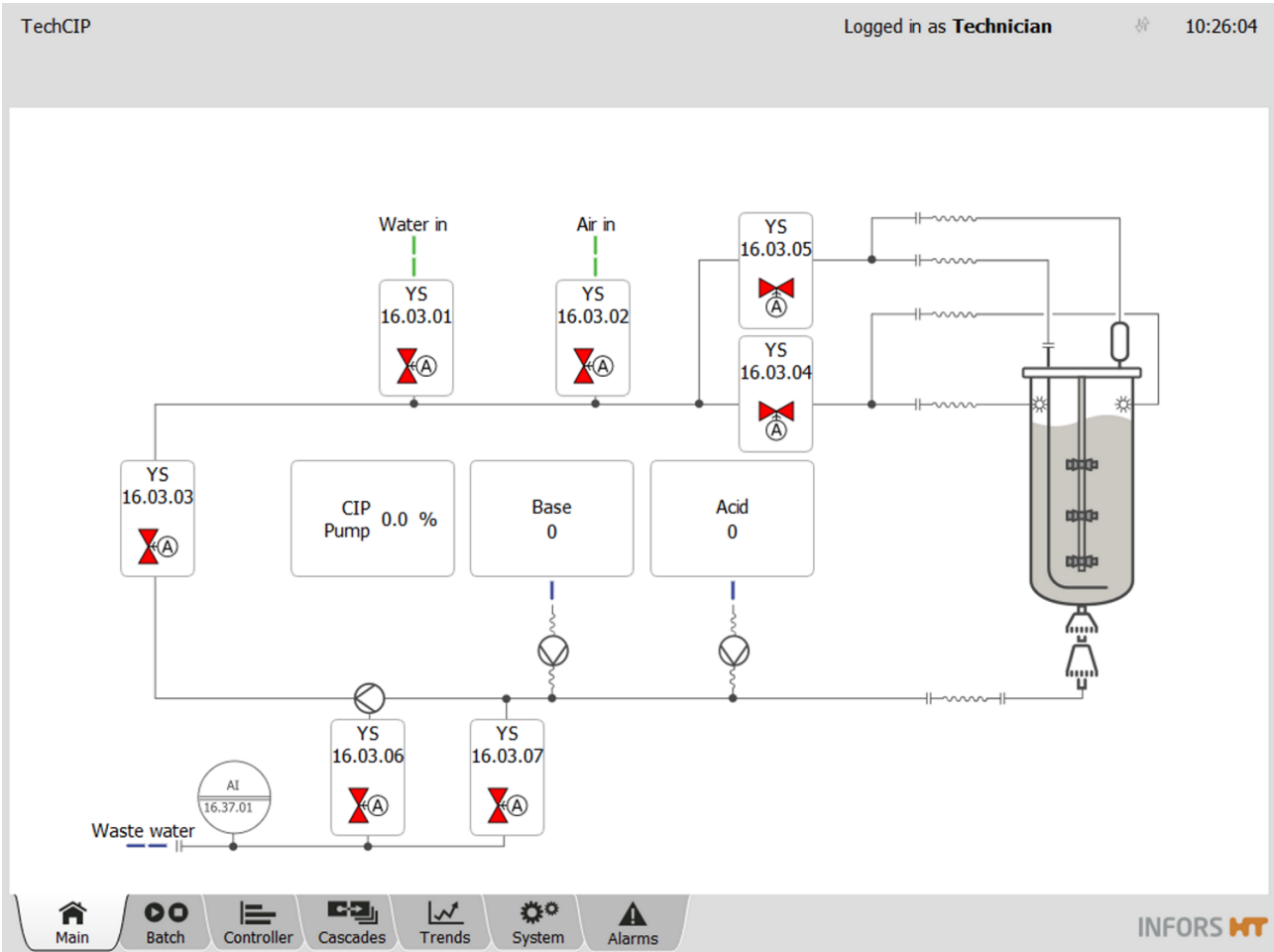
The *Main* menu displays the mobile CIP unit with its pumps and valves. The connections for air and water as well as the connection to the bioreactor are also displayed graphically.
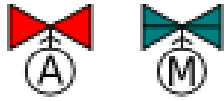
Valves

- The red colour indicates a closed valve.
- The green colour indicates an open valve.
- The letter *A* indicates that the valve is in automatic mode.
- The letter *M* indicates that the valve is in manual mode, i.e. in a "forced" state.
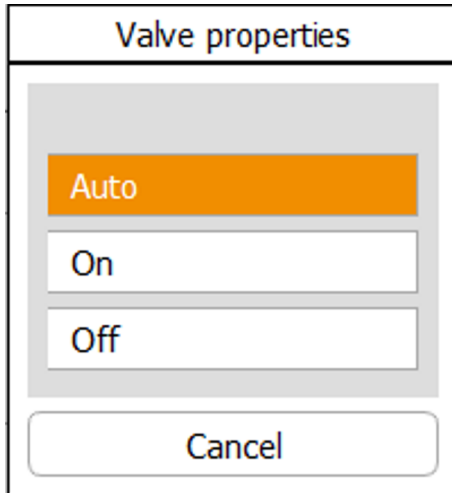
Pressing a valve button opens a dialogue box where you can use **On**, **Off**, or **Auto** to change the valve status for diagnostic purposes.

> **! NOTICE**
>
> Ex-factory, all valves are switched to automatic mode (*Auto*). These settings must not be changed.

Pumps

The two peristaltic pumps *Acid* and *Base* and the CIP pump are displayed as buttons.

- For the CIP pump, it shows whether it is switched on (*100* = ON) or off (*0* = OFF).
- For both peristaltic pumps, the number of revolutions is displayed as standard. If a peristaltic pump is calibrated, the volume delivered is displayed in ml instead.

> The running time of the two peristaltic pumps is set for the corresponding process phases of the CIP process in the configuration dialogue.

Operation

Acid pump properties	
Pump factor:	0.277778
Duration:	61
Value:	16.9444
Reset:	◯

Manual control

FILL	EMPTY

| Cancel | OK |

Pressing one of the pump buttons opens the *pump properties* dialogue box of the selected pump in which the number of revolutions can be reset to zero. The pump factor calculated during a pump calibration is also shown here and can be changed manually. In addition, the **FILL** / **EMPTY** buttons enable manual filling or draining of the pump hose.

6.2.2   Batch – Start Menu

TechCIP	Logged in as **Technician**	⚕ 10:23:20

TechCIP Operation

Start	Stop

Calibrate Pumps

Acid Pump	Stop
Base Pump	Stop

Main | Batch | Controller | Cascades | Trends | System | Alarms

INFORS **HT**
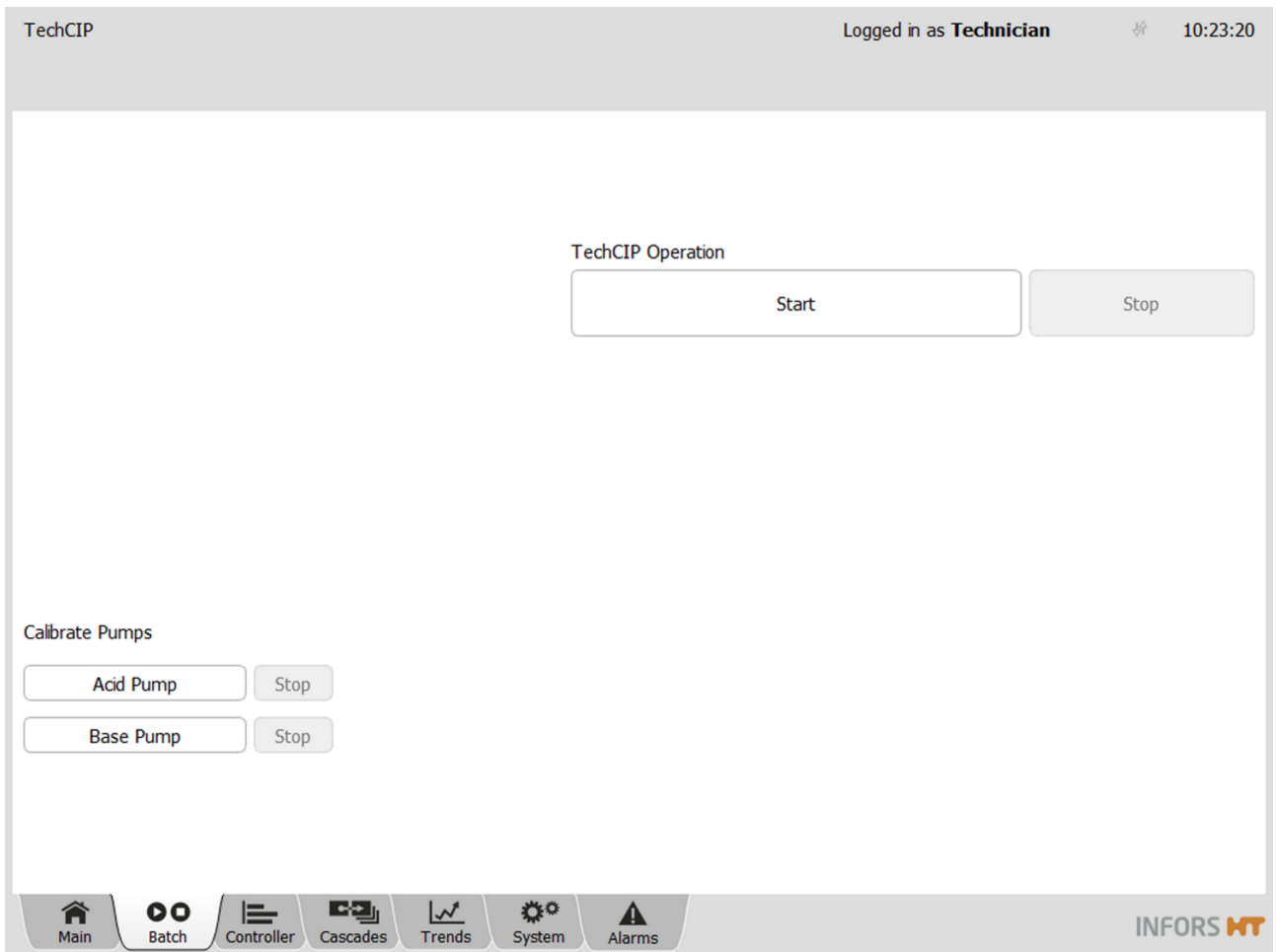
The CIP process is started and stopped in the *Batch* main menu. The two peristaltic pumps can also be calibrated here.

> The pump runtime rather than the volume it transports is relevant for the CIP process. The runtime is set in the various configuration dialogues of the CIP process.

Operation

6.2.3   Controller – Value Display

TechCIP					Logged in as **Technician**		10:31:38

Parameter	Value	Units	Setpoint	Cascade	Output	V-Bar	O-Bar
CIP Pump	0.0	%	100.0		OFF		
Acid	0.0	%	0.0		OFF		
Base	0.0	%	0.0		OFF		
Conductivity	0	μS/cm	--		--		

Main | Batch | Controller | Cascades | Trends | System | Alarms   **INFORS HT**

The *Controller* main menu shows the current values, setpoints and control outputs of the available parameters. This means that the current measured value of the conductivity sensor (*Conductivity*) is visible here. This also shows whether the CIP pump and the two peristaltic pumps are active or not: *100 %* = ON / *0 %* = OFF.

> All settings for the CIP process are made in the various configuration dialogue windows of the process. Parameter settings that are made in the *Controller* menu are automatically overwritten by the process sequences.

6.2.4 Cascades

TechCIP	Logged in as **Technician**	15:25:36

Edit

Clear

Advanced

Setp.Max

Setpoint

Setp.Min

Negative

Output

Main Batch Controller Cascades Trends System Alarms

INFORS HT
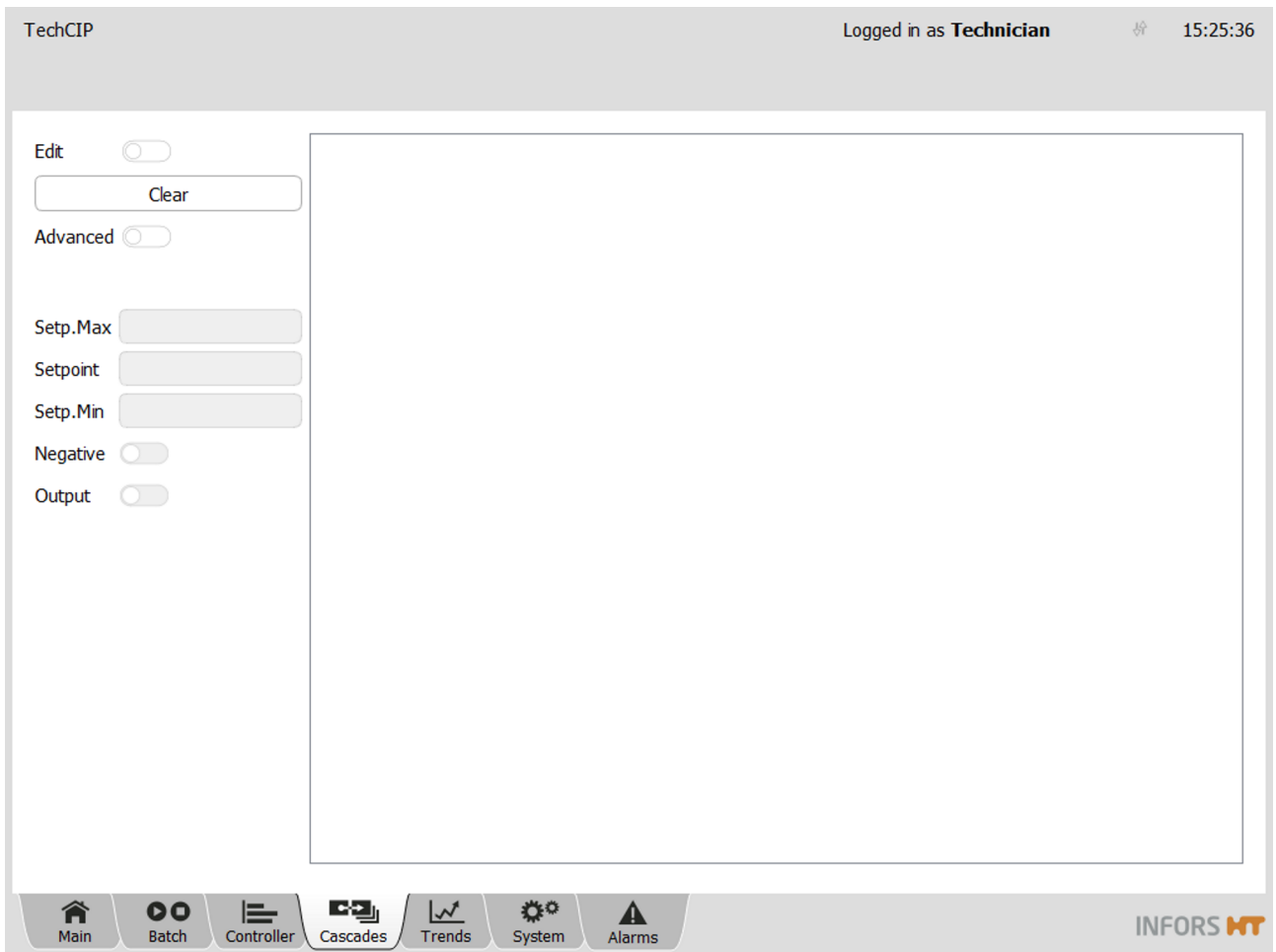
The main menu *Cascades* provides the option of setting up a serial, parallel or mixed cascade control of a parameter.

> This menu is not relevant for the mobile CIP unit.

Operation

6.2.5 Trends – Trend Lines
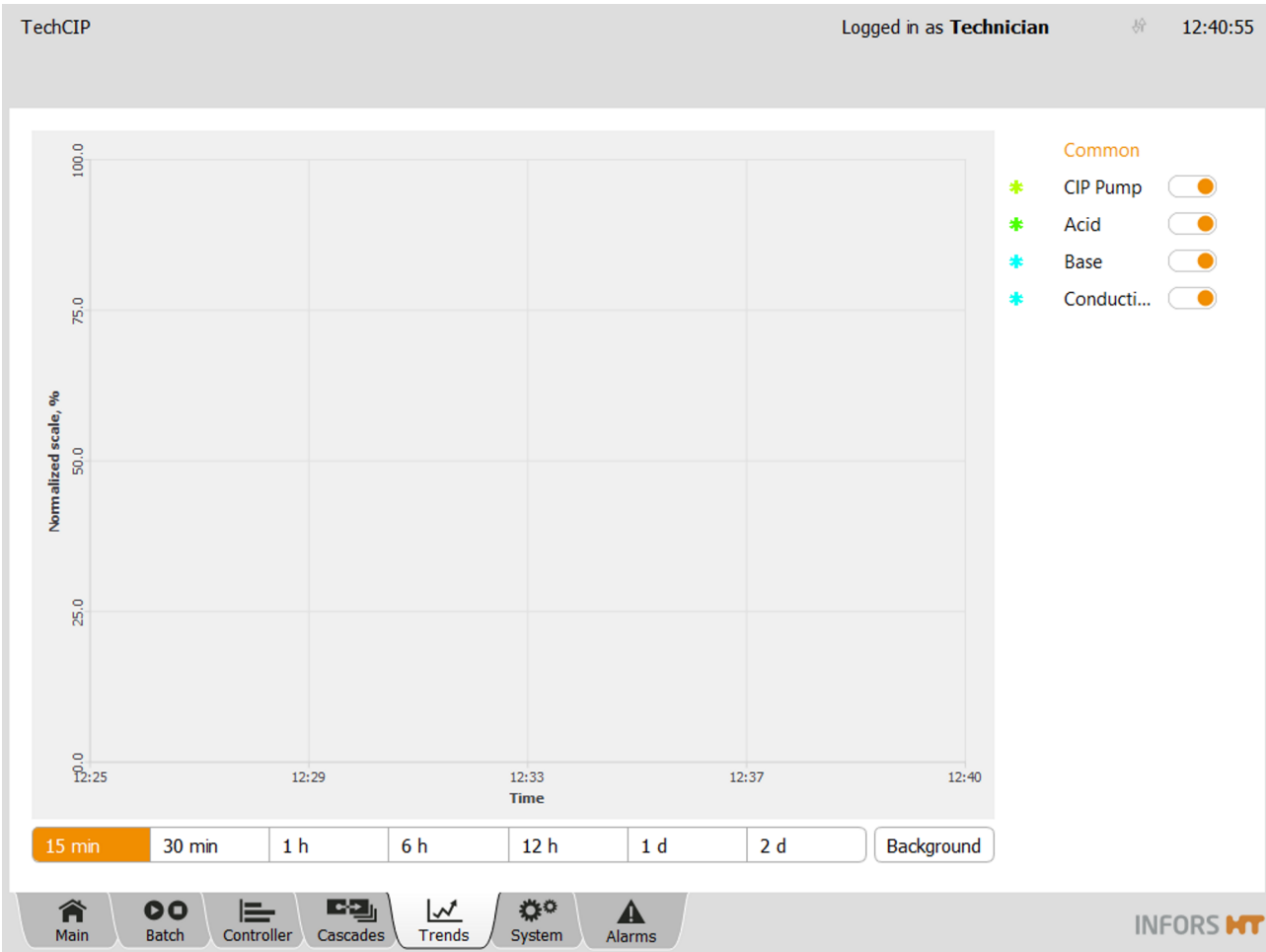
The touch screen operating panel keeps the current values of the parameters in a buffer memory and displays them continuously as a diagram in the *Trends* main menu. This data cannot be archived, edited or exported. However, this data can be transferred to a computer connected via a network, for example, by using eve®, and then be archived there.

The parameters are displayed on the right side of the screen. The display of the trend line of a parameter on the main screen can be shown or hidden by using the **ON/OFF** switch next to the parameter name.

All trend lines shown are normalised to the range of values of the respective parameter. At the upper end of the diagram is the maximum permissible value (= 100 % of the normalised scale), at the lower end is the minimum permissible value (= 0 % of the normalised scale). If a parameter is selected in the list, the Y-axis label of the diagram changes to the permissible value range of the selected parameter. Selecting *Common* via the parameter list resets the Y-axis labelling to the normalised scale.

The time spread of the diagram display can be set from 15 min to 2 days using the buttons below the diagram.

Background can be used to set the background colour (white, grey or black) of the diagram display.

Operation

6.2.6 System – System Settings

TechCIP	Logged in as **Technician** 14:07:03

SN:

Touchfors-Version:
IP address(es):
MAC address(es):
Firmware-Version:
For service, please contact your local dealer www.infors-ht.com

Statistics

Licenses

Valves   Security   Settings   Wipe screen   Shutdown

Main   Batch   Controller   Cascades   Trends   System   Alarms

INFORS **HT**

Device Information

The *System* main menu shows the following information on the device:

- Serial number
- IP address(es) of the system
- Device address (*MAC address*)
- Firmware version
- Internet address (domain) of the manufacturer

Buttons

The top right of the screen has two buttons:

- **Statistics**: Makes it possible to view some statistics of the software communication with the control board, or hardware. The only purpose of this function is to assist the manufacturer's technical support with troubleshooting.
- **Licenses**: Opens a menu with licences of the software libraries used.

Submenus

The menu has 5 buttons, which lead to different submenus:

- *Valves*: Shows the status of the digital outputs
- *Security*: For system login and logout, passwords and user management
- *Settings*: For system and basic settings of the device.
- *Wipe Screen*: Lock the screen for 20 seconds e.g. to clean the screen
- *Shutdown*: For shutting down the system.

Operation

6.2.7 Alarms – Alarm Display

6.2.7.1 Menu Overview

The *Alarms* main menu shows all user and system alarms.

Alarm Display

An alarm is indicated by the alternately light red-dark red flashing *Alarms* tab.

The screen has the following columns:

- *Description*: Describes the alarm.
- *Start* and *End*: Shows the start and end of the alarm with date and time.
- *Confirmed*: Via **Confirm** confirms alarms with date, time and user.

User Alarm

Password Expiry: The password expires. The alarm for password expiry appears for the 10 days leading up to the expiry. The password validity period is set when creating a new user login.

System Alarms

- *Difference in board configuration*: Different control board configuration(s) detected.

- *Invalid modbus map for Parameter …*: Invalid modbus setting for parameter xy.

> ⓘ This alarm can only appear if changes have been made in the modbus settings. Modbus settings can only be changed by the *Service* user group.

- *Requested specialized configuration not installed*: Error occurred while restoring backed up data or installing software updates.

All other system alarms are described in the fault tables (➡ Chapter 7 'Rectifying Faults' on page 92).

6.2.7.2 System Alarm *Difference in board configuration*

A backup of the control board configuration is stored in the touch screen for the device. After a firmware update/control board or touch screen swap, the *Difference in board configuration* alarm might appear. This means that the back up does not match the current configuration.

To be able to select the corresponding configuration, the *Settings* submenu, *Controller Board Configuration* area now shows the **Synchronize differing board configuration** button.
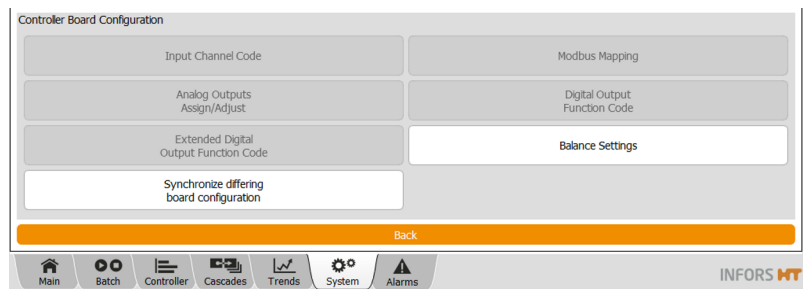
When this function is selected (by pressing the button), the menu appears with two options:

- **Use board configuration**: Replace the backup in the touch screen with the current configuration of the board. This option is useful after changing the touch screen.

- **Use stored board configuration**: The configuration of the board is overwritten with that from the backup. This option is useful after a firmware update or changing the board.

The alarm disappears as soon as the selection function has been executed.

Operation

6.3   Submenus

6.3.1   Valves - Digital Controller Outputs
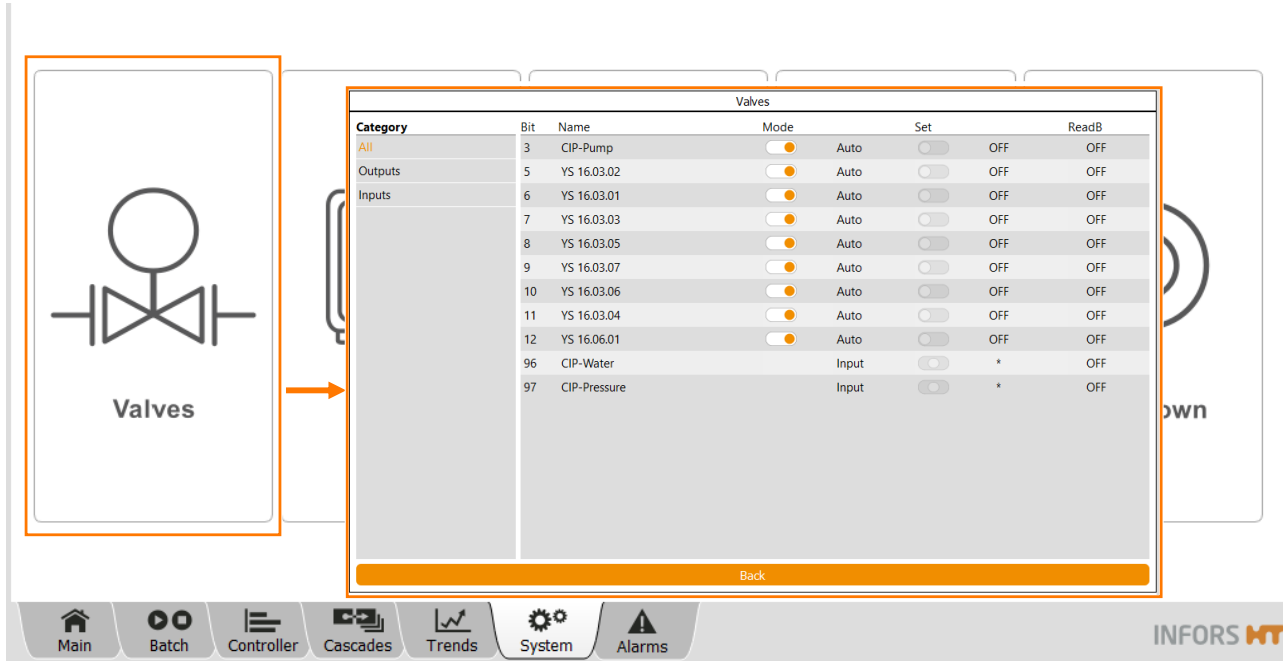
The submenu *Valves* displays the digital outputs and inputs of the control board. The overview is predominantly used for fault diagnosis. All valves and digital outputs are set to automatic mode (*Auto*) ex-factory. These settings must not be changed! The view of all (*All*) digital inputs and outputs or only the display of the inputs or outputs can be selected in column (*Category*). The main column contains:

Bit / *Name*	Channel number and designation	
Mode	*Auto*	Automatic switching
	Manual	Manual switching, outputs are forced, i.e. the automatic switching is thus disabled.
Set (Switching status of the digital output)	*OFF* / *ON*	Output is switched off / on
ReadB (Electronic feedback channel, which confirms the change in status)	*OFF* / *ON*	Readback is switched off / on
If the electrical connection is faulty, it is displayed as *FALSE*.		

6.3.2 Security – User Administration

6.3.2.1 Menu Overview
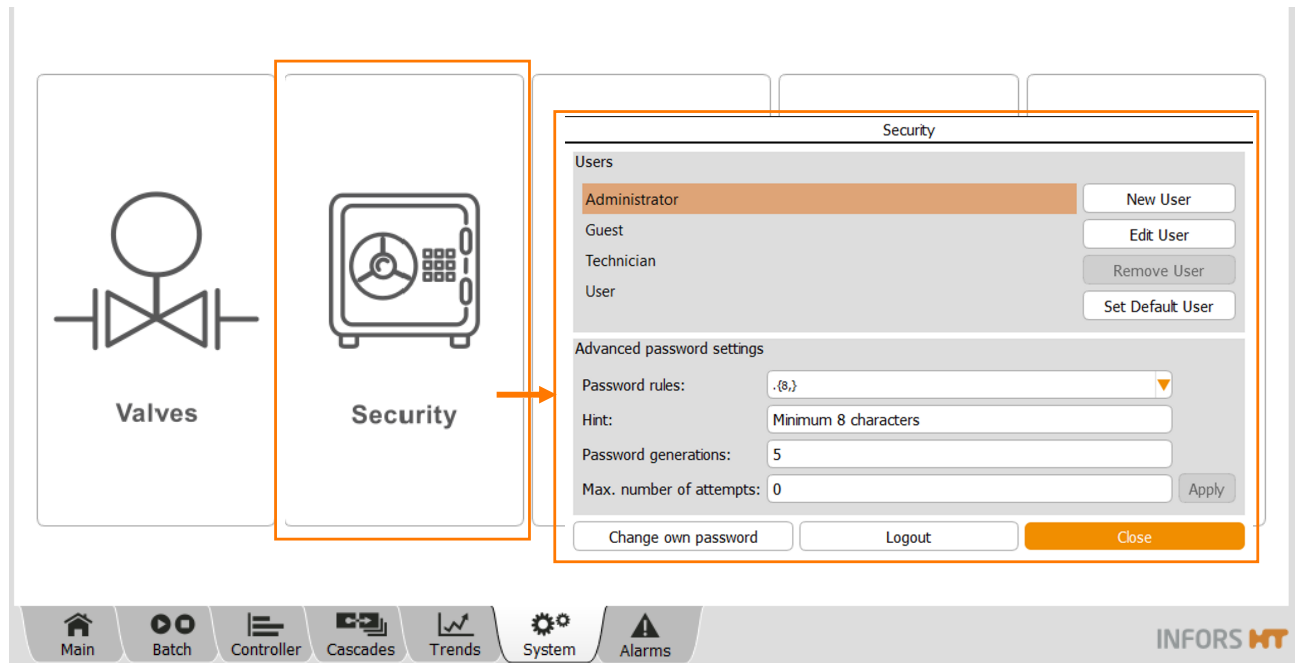
The *Security* submenu is used for logging on and off to and from the system. Users can also be added or deleted here, passwords can be set and access rights can be assigned. The number of functions available depends on the authorisation of the user that is logged on:

- **Login/Logout**: Log in to/out of the system.
- **Change own password**: Change your own password.
- **New User**: Add a new user.
- **Edit User**: Edit user settings.
- **Remove User**: Delete user.
- **Set Default User/Clear Default User**: Set/delete automatic user login.
- **Advanced password settings**: Define password rules for password security.

The different user groups, access rights and functions are described in the following chapters.

6.3.2.2 User Groups

There are five user groups (*Groups*) with different access rights. Ex-factory, a user has been created for each of the groups, except for the *Service* group.

Operation

User groups	User	Password
Guest [1]	*Guest*	No password
Users	*User*	qwertyuiop
Technicians	*Technician*	qwertyuiop
Administrators	*Administrator*	qwertyuiop
Service [2]	--	--

[1] *Without access rights, is logged on automatically if no other user is logged on.*

[2] *Can only be accessed by qualified INFORS HT service technicians and is blocked for all other users.*

> The passwords defined ex-factory should be changed and administrated by the authorised person (*Administrator*) during initial commissioning.

6.3.2.3 Access Rights

Legend

- V (= View) = visible, function cannot be executed. Depending on the function, visible means that only the button or the menu/dialogue box is visible.
- E (= Execute) = visible and function can be executed.
- Blank field = neither visible nor can the function be executed.

TechCIP	User groups				
	Guests	Users	Techn.	Admin.	Serv.
Starting/stopping the CIP process (**Start**/**Stop**)	V	E	E	E	E

PUMPS	User groups				
	Guests	**Users**	**Techn.**	**Admin.**	**Serv.**
Calibrating (*Calibrate Pumps*)	V	E	E	E	E
Resetting the counter (*Reset*)	V	E	E	E	E
Manually setting the pump factor	V	E	E	E	E
Filling/emptying hoses (**FILL**/ **EMPTY**)	V	E	E	E	E

> The runtime of the pumps for the different process phases of the CIP process is set in the configuration dialogue of the CIP process.

PARAMETER options	User groups				
	Guests	**Users**	**Techn.**	**Admin.**	**Serv.**
Setpoint input (*Setpoint*)	V	V	V	V	E
Alarm values and critical values *Upper/Lower Alarm, Upper/Lower Critical*)	V	V	V	V	E
Activating and deactivating parameters (*Output active ON / OFF*)	V	V	V	V	E
Calibrating (*Calibrate*)			V	E	E
PID			E	E	E
Options					E

> All settings for the CIP process are made in the configuration dialogue of the CIP process. Even though some of the above parameter options are visible to the operator, they have no functionality or are overridden by the process sequences.

Operation

CASCADES (*Cascades*)	User groups				
	Guests	**Users**	**Techn.**	**Admin.**	**Serv.**
Setting a cascade	V	E	E	E	E
Setting an advanced cascade (*Advanced*)			E	E	E

> This menu is not relevant for the mobile CIP unit.

TREND LINES (*Trends*)	User groups				
	Guests	**Users**	**Techn.**	**Admin.**	**Serv.**
Changing the display settings	E	E	E	E	E

ALARMS (*Alarms*)	User groups				
	Guests	**Users**	**Techn.**	**Admin.**	**Serv.**
Confirming an alarm (**Confirm**)	V	E	E	E	E

SYSTEM (*System*)	User groups				
	Guests	**Users**	**Techn.**	**Admin.**	**Serv.**
Viewing the statistics of the communication software with the bioreactor hardware (**Statistics**)	E	E	E	E	E
Viewing licences for software libraries (**Licenses**)	E	E	E	E	E

DIGITAL INPUTS/OUTPUTS (*System*, *Valves*)	User groups				
	Guests	**Users**	**Techn.**	**Admin.**	**Serv.**
Switching inputs/outputs manually (*Outputs* / *Inputs*)	V	V	E	E	E

Operation

USER ADMINISTRATION (*System, Security*)	User groups				
	Guests	**Users**	**Techn.**	**Admin.**	**Serv.**
Logging in (**Login**)	E	E	E	E	E
Logging out (**Logout**)		E	E	E	E
Changing the password (**Change Password**)		E	E	E	E
Setting password rules (*Advanced password settings*)				E	E
Adding a new user (**New User**)		V	V	E	E
Removing a user (**Remove User**)		V	V	E	E
Changing user settings (**Edit User**)		V	V	E	E
Setting a default user (**Set Default User**)		V	V	E	EE
List of all users (*Users*)				V	V

SYSTEM SETTINGS (*System/ Settings*)	User groups				
	Guests	**Users**	**Techn.**	**Admin.**	**Serv.**
Network settings (**IP Settings**)	V	V	V	E	E
Changing the date and time (**Change Time**)	V	V	V	E	E
Saving data (**Backup**)			V	E	E
Restoring data backups (**Restore**)			V	E	E
Service menu		V	V	V	E
Exporting log files (**Export Logs**)		E	E	E	E
Setting codes for input channels (**Input Channel Code**)			V	V	E
Assigning/changing analogue outputs (**Analog Outputs Assign/Adjust**)			V	V	E
Setting extended function codes for digital outputs (**Extended Digital Output Function Code**)			V	V	E
Synchronising different board configurations (**Synchronize differing board configuration**)			E	E	E
Modbus settings (**Modbus Mapping**)			V	V	E

Operation

SYSTEM SETTINGS (*System/ Settings*)	User groups				
	Guests	**Users**	**Techn.**	**Admin.**	**Serv.**
Setting function codes for digital outputs (**Digital Output Function Code**)			V	V	E
Balance Settings	V	V	V	E	E

SCREEN LOCK (*System, Wipe Screen*)	User groups				
	Guests	**Users**	**Techn.**	**Admin.**	**Serv.**
Activating a temporary screen lock (**Wipe Screen**)	V	E	E	E	E

SYSTEM SHUTDOWN (*System, Shutdown*)	User groups				
	Guests	**Users**	**Techn.**	**Admin.**	**Serv.**
Shutting down the system (**System, Shutdown**)	V	E	E	E	E

6.3.2.4   Login/Logout – Logging into/out of the System

To log on to the system, proceed as follows:

1. Call up the *System* main menu and tap **Security**.

➡ The *Security* submenu appears.

The drop-down list in the *Login* field contains all users that are pre-set ex-factory and can be selected:

- *User*
- *Technician*
- *Administrator*
- *Other*: Only for INFORS HT service staff
- *Default*: Automatic user login without password input, if previously configured via **Set Default User**.

2. Select the desired user, e.g. *Technician*.
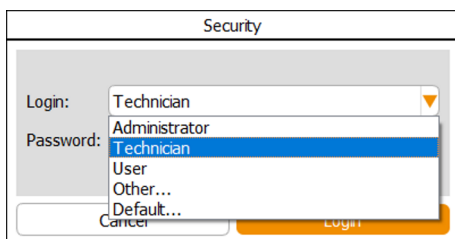
3. ▸ Enter the password, and press **Login**.

➡ The user is logged in.

➡ The *Security* menu now lists the different functions as buttons.

Change own Password (change your own password), **Logout** (log off from the system) and **Close** (leave menu) are available to all users (except for the *Guest* user).
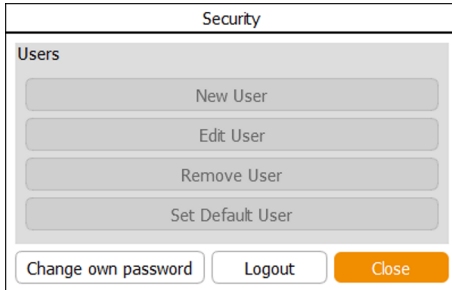
> ⓘ For the *Administrators* user group, all password rules can also be set here, see ➥ Chapter 6.3.2.10 'Password Security - Setting Password Rules' on page 64.

6.3.2.5 Change Own Password – Changing the (Own) Password

Users of all user groups can change their own password. To be able to change their password, the user must be logged in to the system.

To change the own password, proceed as follows:

1. ▸ Call up the *Security* submenu and press **Change own password** .

➡ The *Change password* dialogue box appears.

2. ▸ Enter the old password.

3. ▸ Enter the new password and confirm by entering it again.

➡ All inputs are displayed as dots.
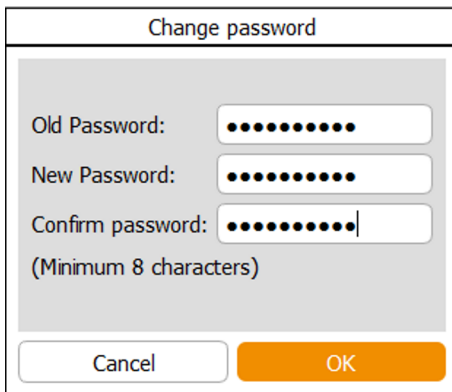
> ⓘ Depending on the password rules set, the password must meet various conditions. Password rules can be configured by *Administrator* users.

4. ▸ Press **OK**.

➡ The dialogue box disappears, the password is saved.

6.3.2.6 New User – Adding a New User

To add a new user, proceed as follows:

1. ▸ As *Administrator* call up the *Security* submenu and press **New User**.

➡ The *New User* dialogue box appears.

Operation

2. ▸ Enter the new user (*Login*).

3. ▸ Select the user group in the *Group* drop-down list.

4. ▸ Enter the password in *New password* and confirm it by entering it again in *Confirm password*.

> Depending on the password rules set, the password must meet various conditions. Password rules can be configured by *Administrator* users.

5. ▸ Select the validity period of the password in the *Validity duration [days]* drop-down list, by choosing between "unlimited", 30, 100 and 365 days.

➡ The corresponding expiry date is then shown in *Expire*.

6. ▸ Activating or deactivating the new user's access rights (*Enable user*); these are activated by default.

> If the function is deactivated, the user has no access rights and a password cannot be assigned.

7. ▸ Activate or deactivate the automatic user logout (*Logout if inactive*) after expiry of a defined time period of screen inactivity, and set a time limit (*Logout after, min*) if necessary.

8. ▸ Press **OK**.

➡ The dialogue box disappears, the new user appears in the user list of the *Security* submenu.

6.3.2.7   Edit User – Changing User Settings

Edit User can be used to change the following settings of an existing user:

- Assign a new user group.
- Change the password.
- Set automatic user logout on screen inactivity after a predefined time in minutes. The lowest user group *Guests* is then set automatically.

To make changes, proceed as follows:

1. ▸ As *Administrator* call up the *Security* submenu.
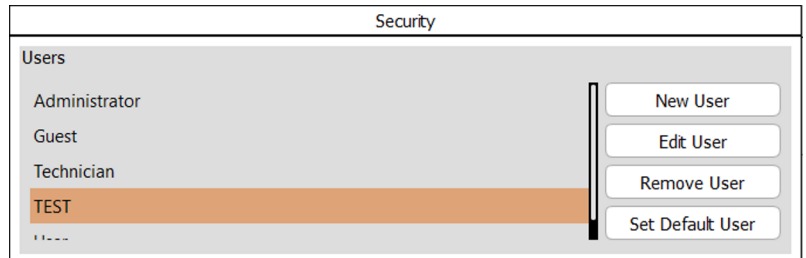
2. ▶ Select the desired user (here: *TEST*) from the selection list and press **Edit User**.

➡ The *Edit User* dialogue box appears with almost identical options to those for entering a new user.

3. ▶ Make the desired settings.

4. ▶ Press **OK**.

➡ The settings are applied, the dialogue box closes.
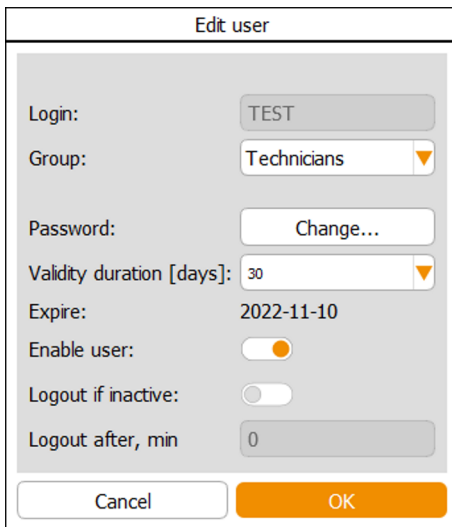
6.3.2.8 Remove User – Deleting a User

To delete a user, proceed as follows:

1. ▶ As *Administrator* call up the *Security* submenu.
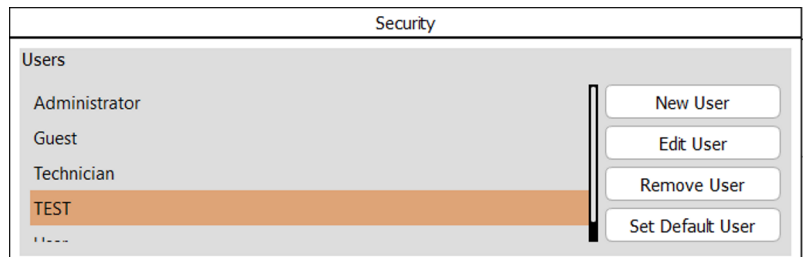
2. ▶ Select the desired user (here: *TEST*) from the selection list and press **Remove User**.

➡ The *Confirmation* dialogue box appears with information and the prompt to confirm the deletion of the user.

3. ▶ Press **OK** to confirm the deletion.

➡ The dialogue box disappears, the *TEST* user has been deleted.
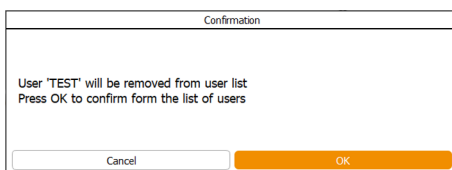
Operation

6.3.2.9 Set / Clear Default User – Setting up Automatic User Login

Set Default User is used to set up an automatic user login. That is, a user can be defined, which will be logged in automatically by the system next time it is switched on. This setting can be deleted via **Clear Default User**.

To do so, proceed as follows:

1. ▷ As *Administrator* call up the *Security* submenu.
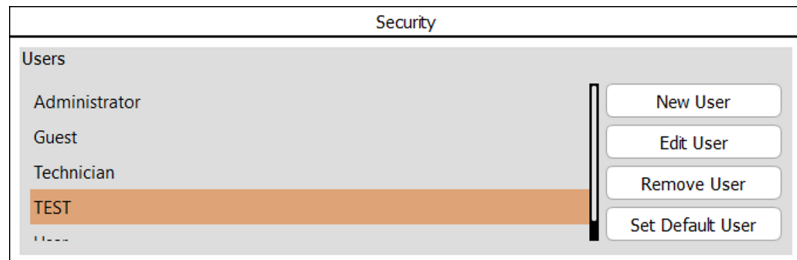
2. ▷ Select the desired user (here: *TEST*) from the selection list and press **Default User**.

➡ The defined user for automatic user login is now displayed with a bold font, the **Set Default User** button is still visible but no longer available.
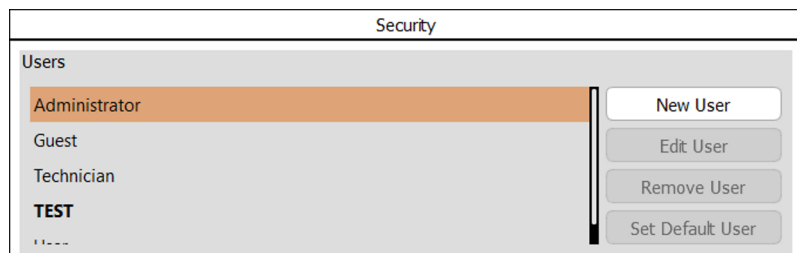

By selecting any other user, all buttons become available for changes again.

By selecting the defined user with automatic user log in, the **Clear Default User** button becomes available instead of **Set Default User**.

6.3.2.10 Password Security - Setting Password Rules

As *Administrator* user, the conditions for creating new user passwords can be configured in the *Security* submenu.

To do so, proceed as follows:

1. ▷ As *Administrator* call up the *Security* submenu.

➡ The lower menu section *Advanced password settings* is now visible and available.
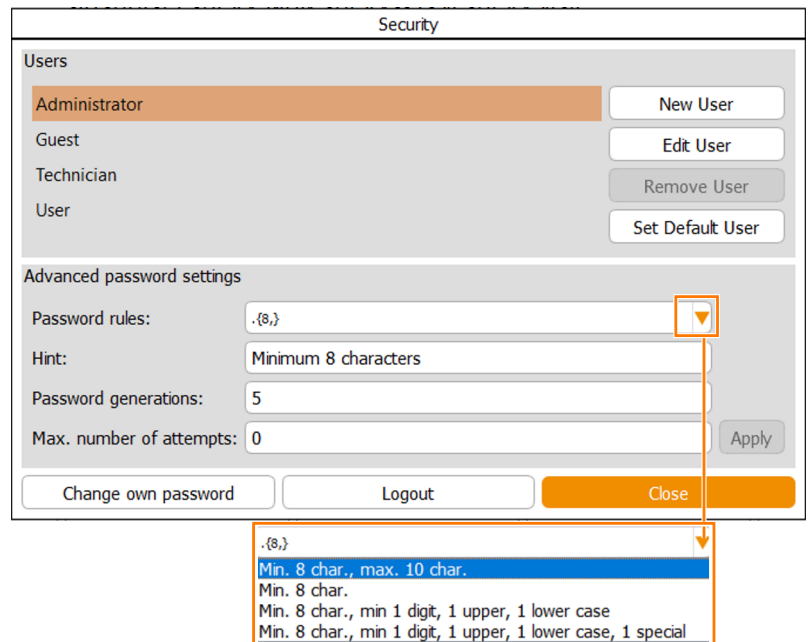
- *Password rules*: A drop-down list with four password rules is available (see figure above). The password must contain at least:
  - 8 characters, which have to include at least 1 number, 1 upper case letter and 1 lower case letter
  - 8 characters, which have to include at least 1 number, 1 upper case letter, 1 lower case letter and a special character
  - 8 characters
  - 8 to a maximum of 10 characters

- *Hint*: When a password is being created, this shows the rules that have to be observed.

- *Password generations*: Specifies the number of new passwords to be created before a password may be reused.

- **Apply**: Apply the rule for new passwords to be created from now on.

2. ▹ Select the rule and enter the number of new passwords to be created.

3. ▹ Press **Apply**.

➡ The rule is saved and is displayed accordingly when the next password is to be created.

4. ▹ Close the *Security* submenu via **Close**.

Operation

6.3.3   Settings – Basic Settings of the Device

6.3.3.1   Menu Overview
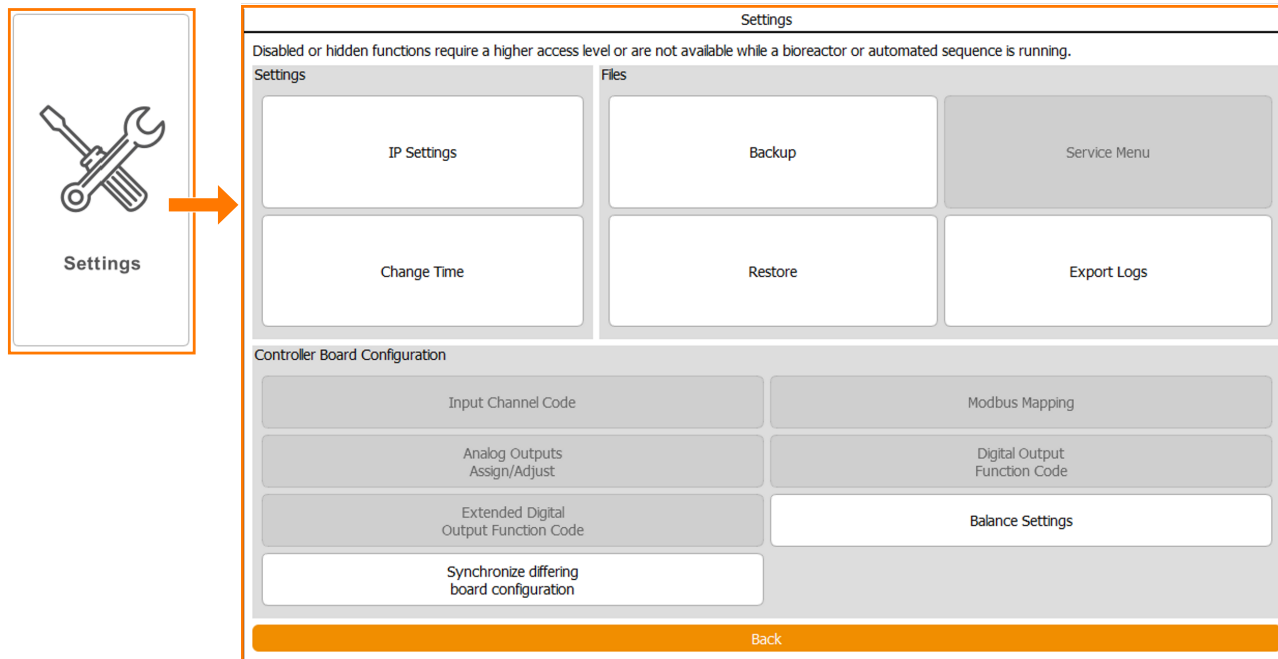
The basic settings of the device are made in the *Settings* submenu. The number of buttons visible and available depends on the authorisation of the user that is logged on. The figure above shows the menu for an *Administrator* user. The menu is divided into three sections with different functions.

Settings

- **IP Settings**: Network settings.
- **Change Time**: Setting the time and date.

Files

- **Backup**: Save data.
- **Restore**: Upload saved data to the system.
- **Service Menu**: Accessible on to INFORS HT service technicians or authorised licensed dealers.
- **Export Logs**: Export log files.

Controller Board Configuration

- **Input Channel Code**: Set codes for input channels.
- **Set codes for input channels**: Assign/change analogue outputs.

- **Extended Digital Output Function Code**: Set functions codes for extended digital outputs.
- **Synchronize differing board configuration**: Synchronize differing board configuration.

> ⓘ This button only appears if a corresponding alarm (*Difference in board configuration*) has been triggered after a firmware update/change of control board or touch screen replacement and is displayed in the *Alarms* main menu. For more information on this subject, see ➥ Chapter 6.2.7.2 'System Alarm *Difference in board configuration*' on page 53

- **Modbus mapping**: Make modbus settings.
- **Digital Output Function Code**: Set function codes for digital outputs.

> ⓘ This manual does not provide any further details on all the functions concerning inputs and outputs, function codes and modbus mappings. Only INFORS HT service technicians or authorised licensed dealers have access to these functions.

- **Balance Settings**: Balance settings.

6.3.3.2   IP-Settings – Network Settings

IP-Settings can be used to configure a network connection. This can be done automatically or manually.

> ⓘ Settings can only be made if a network cable is connected. This manual does not cover how a network is set up or a network connection is established.

To call up this menu, proceed as follows:

1. ▸ As *Administrator* call up the *Settings* submenu.

2. ▸ Press **IP-Settings**.

➡ The *Network Settings* menu appears.

Operation

Network Settings			
Obtain IP settings automatically		Use the following IP settings	

IP address:	192	168	8	162
Subnet mask:	255	255	255	0
Default gateway:	192	168	8	1

Adapter 'Ethernet' connected (192.168.8.162)

Cancel	OK
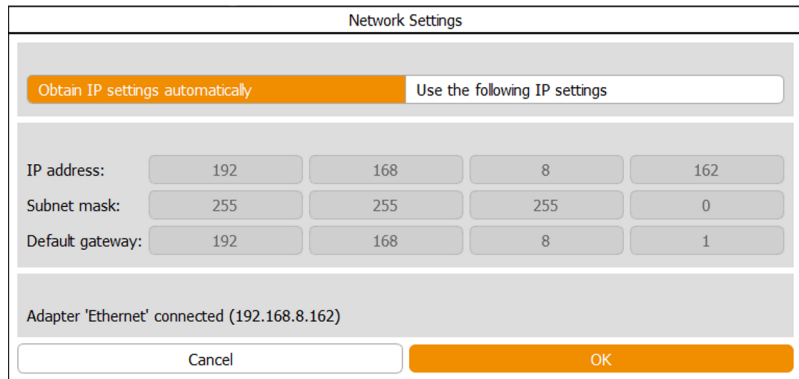
- **Obtain IP settings automatically**: Automatically apply IP settings (default settings). Prerequisite: a DHCP server [1] is available in the network.

- **Use the following IP settings**: Use the following IP settings. An entry can only be made in the following fields after pressing this button.

  – *IP address*: IP address or enter IP address manually.

  – *Subnet mask*: Shows the current subnet mask or lets you enter one manually.

  – *Default gateway*: Shows the default gateway or lets you enter one manually.

> A status message ending with *...connected* indicates that the network connection has been established correctly. If that is not the case (no signal) the error message *No active LAN connection* appears.

[1] *Dynamic Host Configuration Protocol*

6.3.3.3   Change Time – Changing the Date and Time

Change Time is used to adjust the date and time to the system's location. Ex-factory, the system is set to automatic synchronisation with the time server. That is, it is displayed according to the selected time zone. Alternatively, settings can also be made manually.

To make settings, proceed as follows:

1. ▸ As *Administrator* call up the *Settings* submenu.

2. Press **Change Time**.

➡ The *Change System time* dialogue box appears with the configuration set ex-factory:
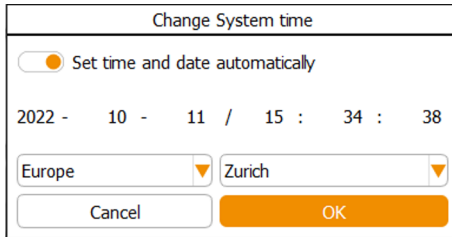
- *Set time and date automatically*: Activate or deactivate automatic time and date setting. This function is activated by default. This makes it possible to select the time zone and the cities assigned accordingly.

- Drop-down lists for selecting time zones and cities: *Europe* and *Zurich* are set as the default.

To make manual settings, proceed as follows:

3. Deactivate automatic time and date setting.

➡ Instead of the drop-down lists, input fields for year/month/day and hours/minutes/seconds appear now.
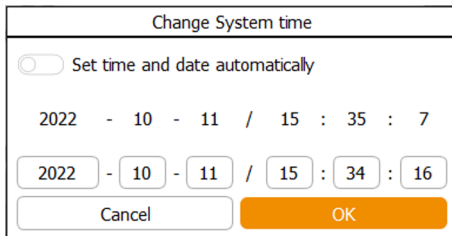
4. Set the desired values and use **OK** to confirm.

➡ The entries are saved and the dialogue box disappears.

6.3.3.4 Backup – Saving Data

The *Backup* function is used to save all settings of the touch screen software and the controller (board) of the bioreactor. This data can then be restored using the *Restore* function.

Please note:

- Data can be backed up to internal storage or a USB stick.

- A data backup can only be executed when all processes have stopped.

- Skip step 1 in the following description if you are not backing up the data onto a USB stick.

To back up data, proceed as follows:

1. Connect the special cable supplied by the device manufacturer to the connection socket on the back of the operating panel and connect the USB stick.

2. As *Administrator* call up the *Settings* submenu.

Operation

Confirmation

You will be switched to backup mode

Press OK to confirm

| Cancel | OK |
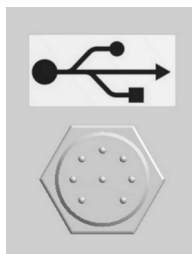
3. ▸ In the *Files* section, press **Backup**.

➡ The *Confirmation* dialogue box appears with a note and a prompt for switching to backup mode.

4. ▸ Press **OK**.

➡ The data backup menu appears.

Touchfors Backup/Restore 3.5.0.32	• •	12:47:3
Select backup destination: 📁 Local		⌄

☐ AutoConfigBackup_TECHCIP_133850_20221006123814.7z
☐ AutoConfigBackup_TECHFORS_133850_20221006082630.7z
☐ ConfigBackup_TECHFORS_S_136175_20221005150136.7z
☐ AutoConfigBackup_TECHCIP_136175_20221005112102.7z
☐ AutoConfigBackup_TECHFORS_136175_20221004091113.7z
☐ AutoConfigBackup_TECHFORS_136175_20221003153709.7z
☐ ConfigBackup_TECHFORS_136175_20220928112802.7z
☐ ConfigBackup_TECHFORS_20220928093223.7z
☐ AutoConfigBackup_TECHFORS_S_20220928092752.7z
☐ AutoConfigBackup_TECHFORS_S_20220927124500.7z
☐ AutoConfigBackup_TECHCIP_20220922133625.7z
☐ AutoConfigBackup_TECHCIP_20220725075045.7z
☐ AutoConfigBackup_TECHCIP_20220718074855.7z
☐ AutoConfigBackup_TECHCIP_20220714142751.7z
☐ AutoConfigBackup_TECHFORS_S_20220713103713.7z
☐ AutoConfigBackup_TECHFORS_20220609135743.7z
☐ ConfigBackup_TECHFORS_131033_20220303140747.7z

Create configuration backup	Create configuration report	Delete backup(s)	Export backup(s)		
				Cancel	Ok

- *Select backup destination*: Choose a storage location, either *local* o *external* (on the connected USB stick).

- **Create configuration backup**: Create a backup file of the current configuration.
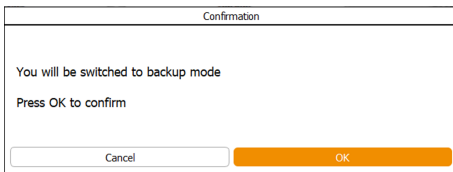
- **Create configuration report**: Output configuration data in a CSV file.

- **Delete backup(s)**: Delete saved backup file(s).

- **Export backup(s)**: Export the backup file(s) from the local storage location to the USB stick.

5. ▸ Select a storage location and press **Create configuration backup** to create the data backup.

➡ The configuration backup is stored as a 7zip file at the selected storage location.

6. ▸ Press **OK** to leave the menu.

7. ▸ Remove the USB stick, if you've used one.

6.3.3.5 Restore – Restoring Data Backups

The *Restore* function enables loading data to the system, which were saved using the *Backup* function. Also factory settings can be restored.

Please note:

- The data is loaded either from the internal storage or from a USB stick, see ➡ Chapter 6.3.3.4 ' Backup – Saving Data' on page 69.
- The *Restore* function can also be executed when all processes have stopped.
- Skip step 1 in the following description if you are not loading the data from a USB stick.

To load data backups to the system, proceed as follows:

1. ▶ Connect the special cable supplied by the device manufacturer to the connection socket on the back of the operating panel and connect the USB stick with the saved data (*Backup* data).
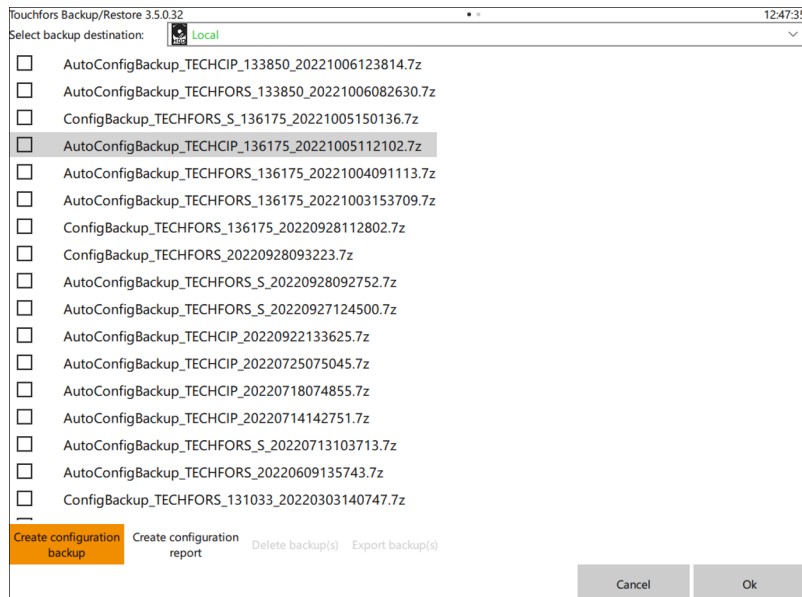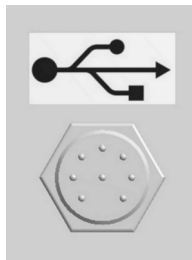
2. ▶ As *Administrator* call up the *Settings* submenu.
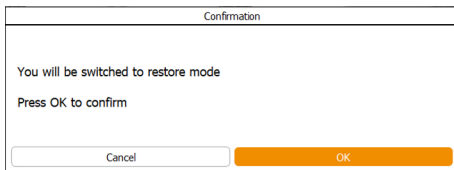
3. ▶ In the *Files* section, press **Restore**.

➡ The *Confirmation* dialogue box appears with a note and a prompt for switching to *Restore* mode.

4. ▶ Press **OK**.

➡ The data backup/restore menu appears.

- **Select configuration for restore**: Select configuration data backup for restoring.
- **Select factory settings**: Select the factory setting.

5. ▶ Press **Select configuration for restore**.

➡ The window for selecting the data source appears in the menu:

Operation
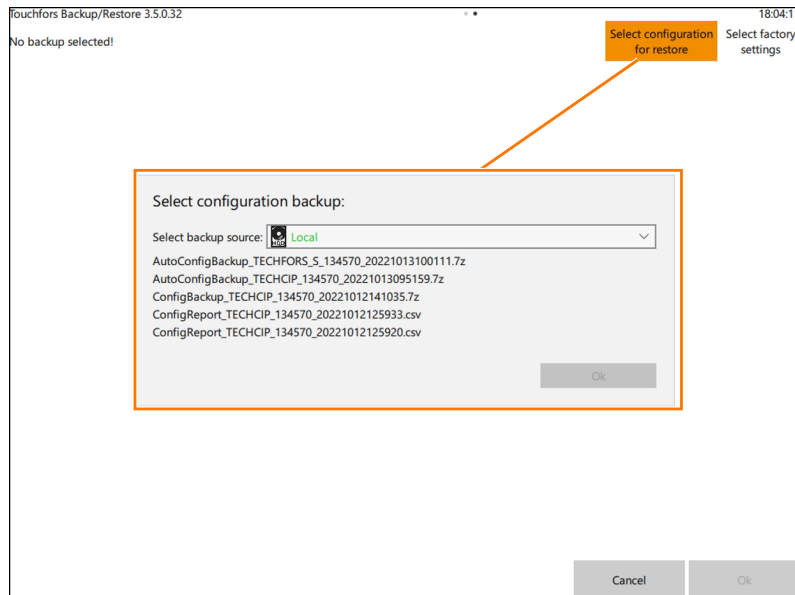
- ■ *Local*: local, internal memory.
- ■ XY/: (Drive): detected connected USB stick.

6. ▸ Select a data source and tap **OK**.

➡ A dialogue box with a confirmation prompt **No** or **Yes** for restoring the data appears.
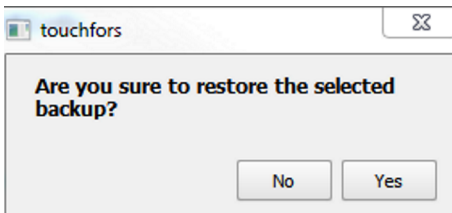
7. ▸ Press **Yes**.

➡ The menu view changes, and the configuration comparison listing appears (not shown here).

> ⓘ The view of the differences within a file is primarily intended as information for the INFORS HT service technician. It represents the differences of the settings file to be restored compared to the version currently used in unified format (also unidiff).

8. ▸ Use **Cancel** to terminate the process or **OK** to execute the data restore.

9. ▸ Remove the USB stick, if applicable.

6.3.3.6 Export Logs – Exporting Log Files

The *Export Log* function can be used to store all log files as well as alarms and error messages on a USB stick.

Please note:

- A USB stick is required for the data export.

- A data export can only be executed when all processes have stopped.

To export the log files, proceed as follows:

1. Connect the special cable supplied by the device manufacturer to the connection socket on the back of the operating panel and connect the USB stick.

2. As *Administrator* or *Technician,* call up the *Settings* submenu.

3. In the *Files* section, press **Export Logs**.

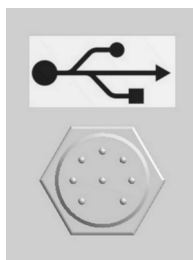➡ The data export is started. As soon as this is done, an *Information* dialogue box appears with the message that the log data has been successfully exported as a zip file (*Log files successfully exported to: xxxxx*).

4. Press **OK** to close the dialogue box.

6.3.3.7 Balance Settings

The *Balance Settings* function is used to set up a maximum of 7 balances that can be connected (via the device manufacturer's Switchbox). Balances must be configured with the correct values. *Baud rate 9600* / *8 bits* / no parity / *2 stop bits*.

To make the settings, proceed as follows:

1. Connect the balance(s) or Switchbox.

2. As *Administrator* call up the *Settings* submenu.

3. Press **Balance Settings**.

➡ The *Balance Configuration* appears with the mentioned configuration values for scales and drop-down lists for selecting the number and type of connected scales.

Operation
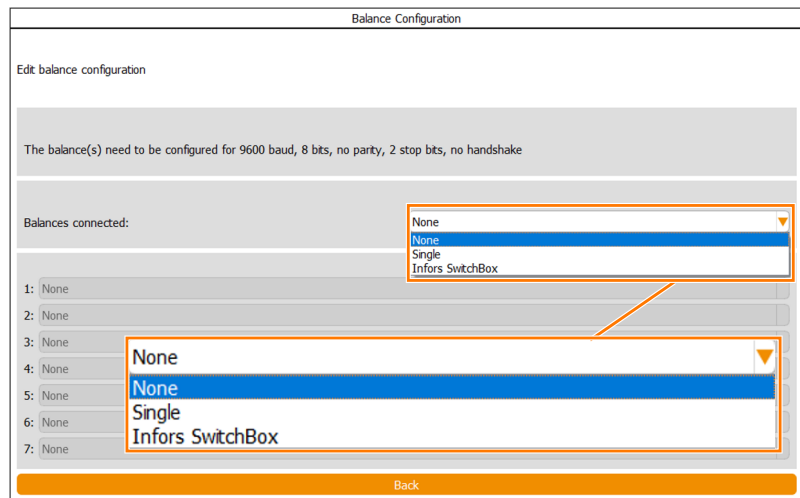
4. ▸ Select the number of balances in *Balances connected*:

- ▪ *None*: None
- ▪ *Single*: One balance; this means that the first drop-down list in the menu area becomes available.
- ▪ *Infors Switchbox*: Switchbox, this makes all 7 drop-down lists in the lower menu section available.

5. ▸ Select the type of balance(s) from the drop-down list(s).

6. ▸ Press **Back**.

➡ The settings are applied, the configuration menu disappears.
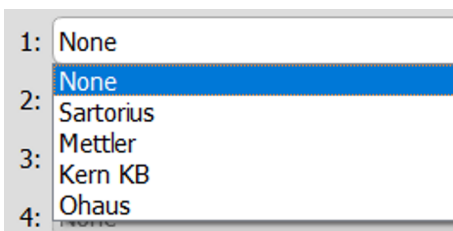
6.3.4 Wipe Screen – (Temporarily) Locking the Screen
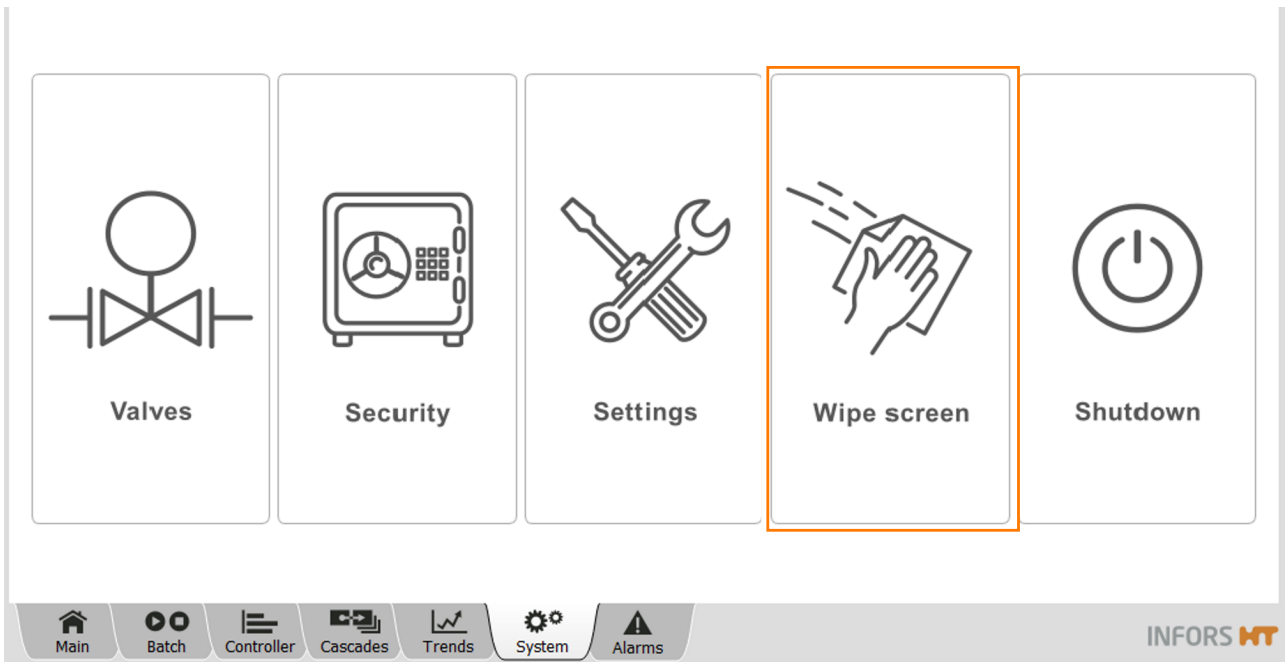
The *Wipe Screen* submenu has only one function: It locks all input on the screen for 20 seconds. This enables you to clean the screen within 20 seconds, if required.

To activate the temporary screen lock, proceed as follows:

▶ Press **Wipe screen**.

➡ The screen turns blank, the remaining time (*Wipe time left*) is displayed.

➡ At the end of this time, the last screen display reappears automatically.

Wipe time left: 17 seconds...

Operation

6.3.5 Shutdown – Shutting Down the System
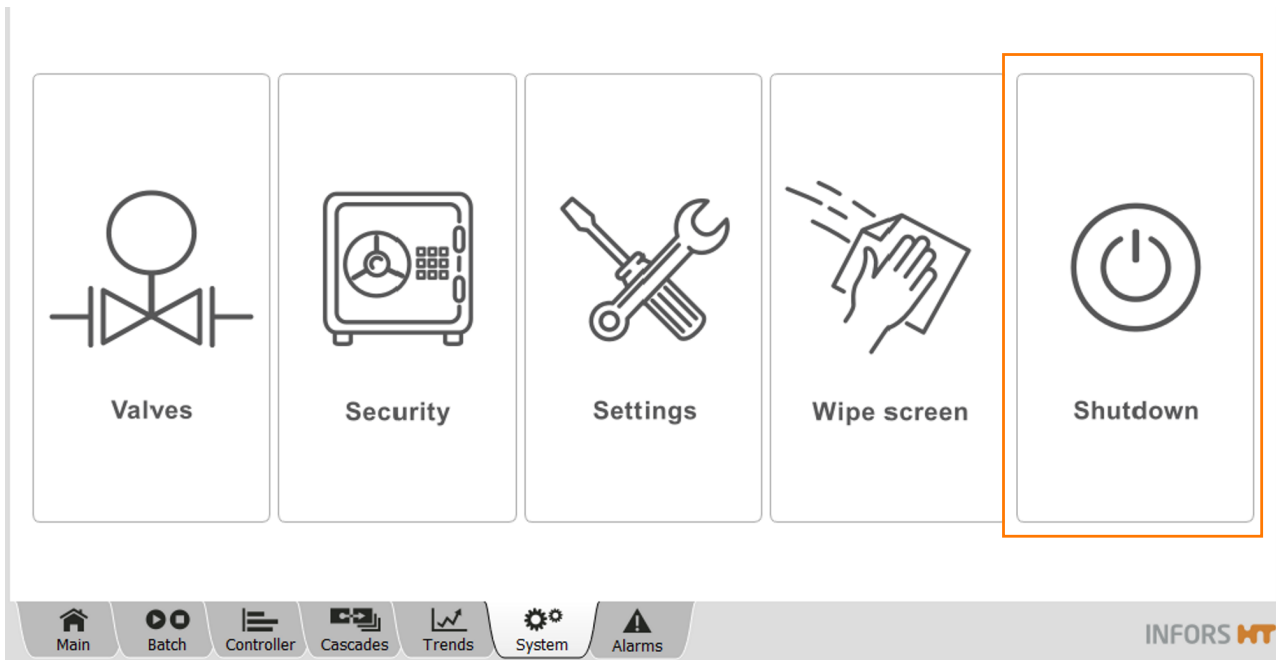
The *Shutdown* submenu has only one function: It shuts down the system. This is only possible when all processes have stopped.

> ALWAYS shut down the system first, then switch off the device o the main switch!

Proceed as follows:

1. ▸ Stop any running process via **Stop** in the *Batch* main menu.

2. ▸ Call up the *System* main menu and press **Shutdown**.

➡ The *Confirmation* dialogue box appears with the query/prompt to confirm the shutdown.

3. ▸ Press **OK**.

➡ The system shuts down.
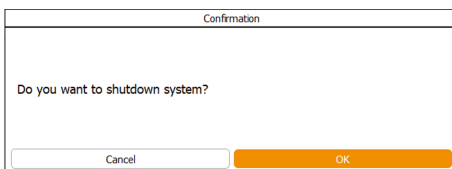
6.4 Pumps and Settings

The two peristaltic pumps *Acid* and *Base* are controlled completely via the sequences of the CIP process. The pump runtime in minutes is displayed for the CIP process. The corresponding settings are made in the configuration dialogue in the CIP process.

6.4.1 Filling and Emptying the Pump Hoses

Press a pump button in the *Main* menu to open the pump dialogue box e.g. *Acid* with **FILL** for filling and **EMPTY** for emptying. The pump runs as long as the corresponding button is pressed.

> ℹ The pump hoses can also be filled and emptied manually via the rocker switches on the instrumentation cabinet, see ➡ Chapter 2.4 'Pumps' on page 20.

6.4.2 Calibrating the Pumps

Calibration of the pumps enables display and recording of the actual pumped volume. The quantity conveyed is stated in ml.

Tools

Provide the following tools:

- Graduated measuring cylinder/cup or balance and empty vessel.
- Reagent bottle equipped with silicone hose and filled with the reagent to be pumped or equally viscous liquid.

Requirements

Please note the following points:

- Always use similar hoses with the same dimensions for calibrating and conveying the media.
- For calibration, use the same or equally viscous liquid as that used for conveying during the process.

Operation

Procedure

To calibrate a pump, e.g. the acid pump (*Acid*), proceed as follows:

1. ▸ Connect the reagent bottle to the pump.

2. ▸ Hang the output side of the hose into the measuring cylinder/beaker or place the reagent bottle on the balance and tare to zero, hang the output side of the hose in the empty vessel.

3. ▸ Fill the hose completely.

4. ▸ Call up the *Batch* main menu and press **Acid Pump**.

➡ The *Calibrate Acid Pump* dialogue box appears and guides you through the calibration step by step.

5. ▸ At step 4 (*Select pump speed*) select the pump speed in percent or manually enter a value via the **Other** option.

> ℹ With the mobile CIP unit, the peristaltic pumps are operated only at 100 % speed. For best results, calibrate the pump with 100%.

6. ▸ At step 5 (*Select calibration time*) select the calibration time or set it manually.

7. ▸ Press **OK**.

➡ Calibration starts. The remaining time (*time left:...*) in h/min/s is displayed next to the **Stop** button that is now available.

As soon as this time has expired, the second dialogue box appears (*Calibrate Acid Pump Part 2*).

8. ▸ Enter the pumped liquid in ml or g (*Enter Weight or Volume*).

➡ After entering the pumped quantity, the automatically calculated pump factor is displayed. For a calibrated pump, the pump factor is always ≠ 1.

9. ▸ Press **OK**.

➡ The dialogue box disappears, the calibrated value is saved. *Completed at* with date and time next to **Stop** shows that the pump has been calibrated as well as when this happened.

6.4.3 Resetting the Pump Counter to Zero

The number of revolutions or the quantity conveyed in ml (if calibrated) of the peristaltic pumps are continuously displayed during the CIP process. After the end of this process, this display continues until a new CIP process is started.

Acid pump properties

Pump factor: 0.277778

Duration: 61

Value: 16.9444

Reset:

Manual control

| FILL | EMPTY |

| Cancel | OK |

However, you can also manually reset the counter to zero:

Press a pump button in the *Main* menu to open the pump dialogue box, in the example on the left, this is the acid pump (*Acid*). The displayed number of revolutions (*Duration*) and quantity conveyed in ml (*Value*) can be reset here via *Reset*.

> By manually changing the pump factor (*Pump factor*) the previously performed calibration is discarded. For a calibrated pump, the pump factor is always ≠ 1.

For details on **FILL** and **EMPTY**, see ➡ Chapter 6.4.1 'Filling and Emptying the Pump Hoses' on page 77.

6.5 CIP Cleaning Process

6.5.1 Safety Notes

Observe the following warning messages before executing the process.

> ⚠ **WARNING**
>
> The vessel of the bioreactor is under pressure during the CIP process! Removing built-in-parts or the vessel top plate may result in liquid splashing out or leaking and/or gases escaping. This can lead to severe burns, burns or poisoning.
>
> Always make sure that the vessel is free of pressure before manipulating built-in-parts and the vessel top plate.

> ⚠ **CAUTION**
>
> Risk of burns due to contact with the hot surfaces! The vessel, piping and associated components of the bioreactor to be cleaned, as well as the piping of the mobile CIP unit, can get hot during the CIP process. Touching these components can lead to burns.

Operation

6.5.2 General Information

The CIP process has five phases:

1)	*Pre-wash* (open circuit)
2)	*Water wash* (closed circuit)
3)	*Base wash* (closed circuit)
4)	*Acid wash* (closed circuit)
5	*Final wash* (open circuit)

Before starting the actual process phases, the connection to the destination system (Techfors-S pilot scale bioreactor) is established. Following that, the individual process phases can be configured. Finally, a dialogue box appears with the preparation work to be performed on the bioreactor and the mobile CIP unit. After that, the programme automatically runs through the process phases up to the final dialogue box.

6.5.3 Process Sequence

The following tables show the five process phases with their individual process steps and the corresponding status messages. These appear next to the running process phase in the touch screen software.

> ℹ️ Process phases 1 to 4 are skipped if the setpoint for the rinsing duration in the corresponding configuration dialogue has been set as = 0. Process phase 5 CANNOT be skipped.

Process phase 1 *pre-wash* (pre-rinsing, open circuit)	
Process step	**Status display**
Tare weight (5 s)	*tare weight + time left* in h:min:s
Pre-wash	*rinsing* + x *repetition(s) left + time left* in h:min:s
Emptying (180 s)	*emptying* + x *repetitions(s) left + time left* in h:min:s

Process phase 2 *water wash* (water rinsing, closed circuit)	
Process step	**Status display**
Tare weight (5 s)	*tare weight + time left* in h:min:s

Operation

Process phase 2 *water wash* (water rinsing, closed circuit)

Process step	Status display
Fill for water wash	*filling up to* + set weight in kg + *current*: current weight measurement in kg
Liquid detection (60 s)	*liquid detection* + *time left* in h:min:s
Water wash	*rinsing* + *time left* in h:min:s
Emptying	*emptying* + *time left* in h:min:s

Process phase 3 *base wash* (base rinsing, closed circuit)

Process step	Status display
Tare weight (5 s)	*tare weight* + *time left* in h:min:s
Filling for the base wash	*filling up to* + set weight in kg + *current*: current weight measurement in kg
Liquid detection (60 s)	*liquid detection* + *time left* in h:min:s
Base addition	*adding base* + *time left* in h:min:s
Heat up to base wash temperature	*heating up to* + set temperature in °C + *current temp*: current temperature value in °C in the bioreactor
Base wash	*rinsing* + *time left* in h:min:s
Emptying	*emptying* + *time left* in h:min:s
Tare weight (5 s)	*(water) tare weight* + *time left* in h:min:s
Fill for water wash	*(water) filling up to* + set weight in kg + *current*: current weight measurement in kg
Liquid detection (60 s)	*(water) liquid detection* + *time left* in h:min:s
Water wash	*(water) rinsing* + *time left* in h:min:s
Emptying	*(water) emptying* + *time left* in h:min:s

Process phase 4 *acid wash* (acid rinsing, closed circuit)

Process step	Status display
Tare weight (5 s)	*tare weight* + *time left* in h:min:s
Fill for acid wash	*filling up to* + set weight in kg + *current*: current weight measurement in kg

Operation

Process phase 4 *acid wash* (acid rinsing, closed circuit)

Process step	Status display
Liquid detection (60 s)	*liquid detection* + *time left* in h:min:s
Acid addition	*adding acid* + *time left* in h:min:s
Heat up to acid wash temperature	*heating up to* + set temperature in °C + *current temp*: current temperature value in °C in the bioreactor
Acid wash	*rinsing* + *time left* in h:min:s
Emptying	*emptying* + *time left* in h:min:s
Tare weight (5 s)	*(water) tare weight* + *time left* in h:min:s
Fill for water wash	*(water) filling up to* + set weight in kg + *current*: current weight measurement in kg
Liquid detection (60 s)	*(water) liquid detection* + *time left* in h:min:s
Water wash	*(water) rinsing* + *time left* in h:min:s
Emptying	*(water) emptying* + *time left* in h:min:s

Process phase 5 *final wash* (final rinsing, open circuit)

Process step	Status display
Final wash	*rinsing* + *time left* in h:min:s
	If the setpoint for addition repetition(s) > 0: additional status message: *x repetition(s) left*
Emptying	*emptying* + *time left* in h:min:s
	If the setpoint for addition repetition(s) > 0: additional status message: *x repetition(s) left*
Pressure decrease	*pressure decrease* + *time left* in h:min:s

Status *Wait for cycle end*   During the process phases *water wash* to *final wash* the programme also waits for the cycle end after the rinsing or emptying time has already ended.

Water Rinses

All setpoints (except for the rinsing time!) of the *water wash* process phase also apply to the water rinses during the *base wash* and *acid wash* process phases. This ensures that water rinsing is always performed during these two process phases, even if the *Pre-wash* process phase is skipped.

Conductivity Measured Values Exceeded

The defined rinsing sequence of the last process phase *final wash* can be repeated up to three times (enter *Max. repetitions*) to achieve the desired conductivity. If the setpoint is exceeded during the last possible cycle, an alarm is triggered and the process is safely aborted.

Status Displays on the Bioreactor

During the entire CIP process, the status display of the bioreactor shows *in progress since...h:min:s*. As soon as the process is complete, the status message *stopped at* + date and time appears.

6.5.4 Process Configuration

> Process phases 1 to 4 are skipped if the setpoint for the rinsing duration in the corresponding configuration dialogue has been set as = 0. Process phase 5 CANNOT be skipped.

Process phase 1 *pre wash*

Input field	Value range	Unit
Rinsing time (rinsing duration)	0 to 120	min
Repetition(s) (number of repetitions for pre-rinse cycle)	0 to 10	--

Process phase 2 *water wash*

Input field		Value range	Unit
Rinsing time (rinsing duration)		0 to 120	min
Filling weight (fill weight of the bioreactor):	15 l TV	5 to 10	kg
	30 l TV	10 to 20	kg
	42 l TV	15 to 30	kg
Stirrer (rotation speed bioreactor stirrer)		20 to 300	min^{-1}

Operation

Process phase 2 *water wash*

Input field	Value range	Unit
Emptying time (time for emptying the vessel)	3 to 120	min

Process phase 3 *base wash*

Input field		Value range	Unit
Rinsing time (rinsing duration)		0 to 120	min
Filling weight (fill weight of the bioreactor):	15 l TV	5 to 10	kg
	30 l TV	10 to 20	kg
	42 l TV	15 to 30	kg
Base adding time (time for adding the base via the base pump of the mobile CIP unit)		0 to 60	min
Temperature (rinsing temperature with base with the temperature measured on the bioreactor)		max. 79	°C
Stirrer (rotation speed bioreactor stirrer)		20 to 300	min^{-1}
Emptying time (time for emptying the vessel)		3 to 120	min

Process phase 4 *acid wash*

Input field		Value range	Unit
Rinsing time (rinsing duration)		0 to 120	min
Filling weight (fill weight of the bioreactor):	15 l TV	5 to 10	kg
	30 l TV	10 to 20	kg
	42 l TV	15 to 30	kg
Acid adding time (time for adding the acid via the acid pump of the mobile CIP unit)		0 to 60	min
Temperature (rinsing temperature with acid with the temperature measured on the bioreactor)		max. 79	°C
Stirrer (rotation speed bioreactor stirrer)		20 to 300	min^{-1}

Process phase 4 *acid wash*		
Input field	**Value range**	**Unit**
Emptying time (time for emptying the vessel)	3 to 120	min

Process phase 5 *final wash*		
Input field	**Value range**	**Unit**
Rinsing time (rinsing duration)	3 to 120	min
Emptying time (time for emptying the vessel)	3 to 120	min
Max. repetitions (Max. repetitions of the final rinse)	0 to 3	--

6.5.5 Before Starting the Process

Before the process is started, check and ensure the following:

General (Bioreactor and Mobile CIP Unit)

- All the necessary power supplies are available and ready to operate.
- All power supply lines have the correct connection pressures.
- Unused connections and ports are closed in a pressure-tight manner.
- The device is switched on at the main switch; the system is ready for operation.

Hose Lines/CIP Lances/Reagent Bottles

- Reagent bottles are prepared and connected.
- The hose pair with the CIP lances is connected.
- The hose pair for inlet air and exit gas is connected.
- The hose line for the harvest/sample valve *05.12.01* is connected.

Bioreactor

- The air bleed valve is mounted in the vessel top plate and the hose line is installed in backpressure-free drain.
- Valve *02.16.01* on the vessel top plate is switched to position *OP* (= *Operation*).
- The harvest/sample valve *05.12.01* is open.
- The mechanical seal is lubricated.

> **❗ NOTICE**
>
> Running the mechanical seal dry will damage it. Hence the mechanical seal must always be lubricated.

Bioreactor Optional

- Exit gas analysis option: The 3-way ball valve *03.41.01* is set to the position for sterilisation (= direct output).

> **❗ NOTICE**
>
> Moisture ingress into gas sensors for exit gas analysis can damage them or falsify the measurement results.
>
> The exit gas line leading through the exit gas analysis must be closed during sterilisation.

- Switchover tap water / chilled water option: The 3-way ball valves *01.41.01* and *01.41.02* are set to the position *Tap Water* (cooling cycle with tap water) or position *Chilled Water* (cooling cycle with chilled water).

> **❗ NOTICE**
>
> An incorrect position of the ball valves for tap water/chilled water can lead to overfilling or overflowing of the cooling circuit!

- Resterilisable feed line option: The feed line is removed, the port in the vessel top plate is closed with a blanking plug.

6.5.6 Starting the Process and Process End

To start the process, proceed as follows:

1. ▷ In the *Batch* main menu, press **Start**.

➡ The *Connection* dialogue box appears for the connection to the bioreactor.

- *IP address or hostname*: Enter the IP address of the bio-reactor to be cleaned. This input is also required the first time a connection is established.

- *Name* (optional): Assign a bioreactor name to the IP address. This function is optional. It is useful if more than one bioreactor (sequentially!) is to be cleaned with the mobile CIP unit.

- *Use*: Activate or deactivate the connection with the IP address or bioreactor from the list.

- **Add** / **Delete**: Add a bioreactor to the list/delete a bio-reactor from the list.

- **Connect**: Connect to the bioreactor.

- **Test**: Test the connection to the bioreactor.

2. ▶ When connecting for the first time: Select the bioreactor or enter the IP address from the bioreactor.

> ⓘ If necessary, first perform the test for the connection to the bioreactor via **Test** or proceed directly to step 3.

3. ▶ Press **Connect**.

➡ The configuration dialogue appears.

Operation

The 5 process phases with the respective input fields can be selected freely via the tab pages. By choosing **Next** they are called one after the other in the order of the process flow.

4. ▸ Enter the setpoints for all process phases.

5. ▸ Press **OK**.

➡ The dialogue box for user interaction appears with more or fewer steps to be performed depending on the configuration of the bioreactor.


The figure shows as an example the dialogue box of a Techfors-S with an optional switchover from tap water to chilled water (step 10).

6. ▶ Check and make sure that all listed steps have been performed, execute them if necessary.

➡ At the same time as the described dialogue box of the mobile CIP unit, the corresponding dialogue box for user interaction appears on the Techfors-S bioreactor.

TechCIP Operation: user interaction required
Confirm preparation
OK
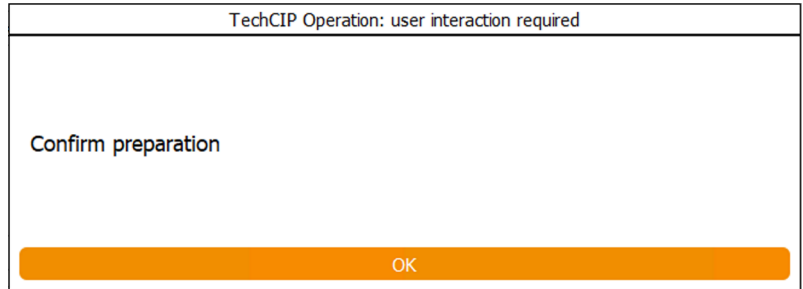
The process cannot be started without confirming the dialogue box.

7. ▶ Once all listed steps have been performed: Press **OK** in both dialogue boxes.

➡ The program now runs through the process phases until the final rinse is emptied.

As soon as the time for the last emptying of the final rinse has elapsed, the last dialogue box for user interaction appears.

TechCIP Operation: user interaction required
Close harvest / sample valve 05.12.01
OK
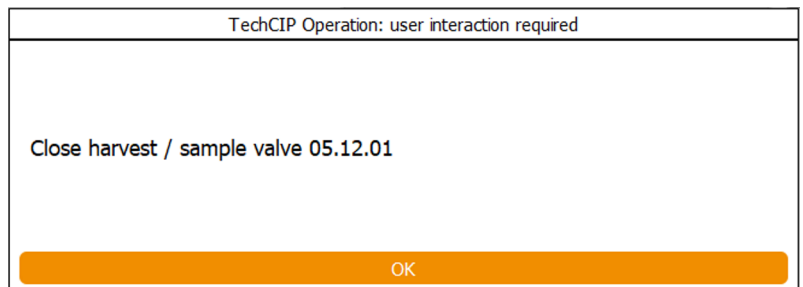
8. ▶ Close the harvest/sample valve *05.12.01* on the bioreactor.

9. ▶ Press **OK**.

➡ The process is completed, and the *completed at* + date and time display appears. The network connected to the bioreactor is automatically disconnected.

Operation

6.5.7   Process Abortion

There are two different types of process abortions:

■ Automatic process abortion triggered by the system due to a faulty system state.

■ Manual process abortion, triggered by the operator via **Stop** next to the **Start** button.

In any case, a safe abortion defined via the system takes place. A process abortion is shown as *aborted at* with date and time.

6.6   Emergency Shut-Off – Shut Down in Case of an Emergency

To shut off the mobile CIP unit in dangerous situations, proceed as follows:

1. ▸ Immediately switch off the mobile CIP unit on the main switch.

➡ The running CIP process in the mobile CIP unit and bioreactor is terminated.

➡ The mobile CIP unit and bioreactor are set to idle state.

➡ The software connection to the bioreactor is connected, the status message *TechCIP Operation: stopped at* + date and time + *communication error* appears there.

2. ▸ If necessary, trigger the emergency shut-off on the bioreactor via the main switch.

6.7 Switching On Again after Shutdown

> ⚠ **CAUTION**
>
> Premature restarting when the emergency shut-off situation has not yet been rectified can be dangerous and result in material damage.

After faults and the emergency shut-off situation have been rectified:

1. ▸ Switch on the mobile CIP unit on the main switch.

➡ The *System restarted after a power failure* system alarm appears.

> ⓘ If additional switches for the power supply/interruption have been fitted on the operating side, the internal safety regulations for this must be observed.

2. ▸ If an emergency shut-off has been triggered at the bioreactor, switch the device on again via the main switch.

7 Rectifying Faults

The following chapter describes possible reasons for faults and how to resolve them. Reduce the service intervals in correspondence with the actual loads if faults become increasingly common. Contact the manufacturer or licensed dealer in case of faults that cannot be resolved by following the notices below.

7.1 Fault Tables

7.1.1 General Faults

Fault description	Cause	Remedy	Personnel
The device does not work, the green power indicator light is not lit, the screen of the operating panel remains dark.	The device is not switched on.	Switch the device on via the main switch.	Operator
	Power supply to device interrupted.	**1.** Check if the plugs are plugged in correctly. **2.** Check the mains connection.	Operator
	Circuit breaker(s) has/have tripped.	**1.** Open the instrumentation cabinet. **2.** Switch on both circuit breakers. If they are triggered again consult an INFORS HT service technician.	Technician
The green power indicator light is lit, the screen of the operating panel remains dark.	The screen of the operating panel is switched off.	Switch on the screen of the operating panel via the **ON/OFF** key on the monitor.	Operator
	The power cable is not connected to the operating panel.	Connect the power supply cable to the DC terminal of the operating panel.	Operator
No communication between the device and the operating panel (alarm *no communication*)	iDDC-Bus cable (display cable) is not connected to the operating panel.	Connect the iDDC-Bus cable to the *COM1* connection (labelled *RS-485*) of the operating panel.	Operator
	iDDC-Bus cable (display cable) is not connected to the controller in the instrumentation cabinet.	**1.** Open the instrumentation cabinet. **2.** Connect the iDDC-Bus cable (display cable) to the controller.	Technician

7.1.2   Process Faults

Fault description	Cause	Remedy	Personnel
Unable to establish communication between mobile CIP unit and bioreactor. The message *Failure, Timeout* appears in the *TechCIP Operation: connection* dialogue box.	The IP address of the bioreactor is incorrect.	1. Check the IP address of the bioreactor and, if necessary, enter it correctly in the connection dialogue box. 2. Test the connection via **Test** in the connection dialogue box. 3. Establish the connection via **Connect** in the connection dialogue box in the usual manner.	Operator
The CIP process cannot be started. The status message *TechCIP sequence on*: (NAME of destination system = bioreactor) + *SN* (serial number) *not enabled!* appears.	The bioreactor is not in idle state.	If applicable: 1. Stop or end the running process in the bioreactor (for details on the processes, refer to the separate operating manual of the bioreactor). 2. Restart the CIP process.	Operator
The CIP process is aborted. System alarm mobile CIP unit and bioreactor: *TechCIP communication error*.	The communication between the mobile CIP unit and the bioreactor has been interrupted.	1. Check the network connection between the mobile CIP unit and the bioreactor; connect a network cable, if applicable. 2. Restart the CIP process.	Technician
	The emergency shut-off was triggered on the bioreactor via the main switch.	1. Resolve the emergency shut-off situation. 2. Contact an INFORS HT service technician for emptying the system.	Technician

Rectifying Faults

Fault description	Cause	Remedy	Personnel
The CIP process is aborted. System alarm mobile CIP unit: *TechCIP no liquid during liquid detection.*	The liquid level in the CIP circuit is too low.	**1.** Ensuring venting via the air bleed valve *16.06.01* (bioreactor vessel top plate), mount the valve, if applicable. **2.** Ensure that the water supply (*WFI*) for TechCIP is switched on, switch on if applicable. **3.** Restart the CIP process. If the alarm occurs again, contact an INFORS HT service technician.	Operator
The CIP process is aborted. System alarm mobile CIP unit: *TechCIP no liquid during rinse.*	No liquid in the CIP circuit.	**1.** Check the supply lines and tube/hose connections for leaks, if necessary, fasten hose the lines/piping correctly or replace hose lines. **2.** Restart the CIP process. If the alarm occurs again, contact an INFORS HT service technician.	Technician
The CIP process is aborted. System alarm mobile CIP unit: *Pressure too low for 30 s.*	The pressure in the CIP circuit is too low. (Pressure monitoring always starts 1 min after the start of each rinsing sequence).	**1.** Check the supply lines and tube/hose connections for leaks, if necessary, fasten hose lines/piping correctly or replace hose lines. **2.** Restart the CIP process. If the alarm occurs again, contact an INFORS HT service technician.	Technician
System alarm mobile CIP unit: *System restarted after power failure.* System alarm target system: *TechCIP communication error.*	System restart after switching on after emergency shut-off (= power interruption).	**1.** Ensure that the emergency shut-off situation has been resolved. **2.** Contact an INFORS HT service technician for emptying the system.	Technician
	System restart after power interruption.	Contact an INFORS HT service technician for emptying the system.	Technician

7.2 Device Response in Case of a Power Interruption

If the power supply to the mobile CIP unit is interrupted, it is immediately de-energised and in a safe state. All valves are closed without power.

The system alarm *Restart after power failure* indicates that there has been a power interruption. However, the alarm provides no information on the duration of the event.

7.3 Returning for Repair

The provider must return the device 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.

> If the device, component or accessory has to be returned to the manufacturer for repair, a legally compliant declaration of decontamination is required for the safety of all parties involved and to comply with legal requirements (➡ Chapter 1.9 'Declaration of Decontamination' on page 14).

8 Cleaning and Maintenance

8.1 Maintenance Plan

> ⚠️ **WARNING**
>
> Failure to observe the maintenance plan bears a significant risk. Failure of wear parts can leads to leaks. Leaking liquids can cause injuries or property damage.
>
> Users are responsible for compliance with the maintenance plan; failure to comply with it will result in exclusion of liability (see GTC).

The following sections describe the maintenance work that is required for optimal and fault-free operation.

If increased wear is detected during regular checks, the required maintenance intervals must be shorted in accordance with the actual signs of wear. Contact the manufacturer if you have questions about maintenance work and intervals.

Interval	Maintenance work	Personnel
Prior to each use	Check the supply and connection hoses as well as the hoses of the reagent bottles and pump hoses for damage, replace if necessary.	Operator
	Check the reagent bottles for damage such as hairline cracks, scratches etc., replace if necessary.	Operator
After every cleaning process (CIP)	Thoroughly clean the hoses of the reagent bottles and pump hoses, and replace them as a preventive measure according to the user's requirements.	Operator
Every 6 months	Replace the O-ring of the air bleed valve and the flat gaskets of the reagent bottles. Reduce the maintenance interval if necessary	Operator
Annually	Replace flat gaskets and valve diaphragms.	Technician
	Have the pressure sensor calibrated by the sensor manufacturer.	Technician
	Recommendation: Complete device maintenance.	INFORS HT service technician or licensed dealer
As required	Clean the reagent bottles.	Operator
	Wipe down the surfaces of the instrumentation cabinet and operating panel.	Operator

Interval	Maintenance work	Personnel
As required	Clean the cooling fins and fan of the CIP pump motor.	Operator

8.2   Cleaning the Surfaces of the Instrumentation Cabinet and Operating Panel

If necessary, the surfaces of the instrumentation cabinet and operating panel can be cleaned.

> **! NOTICE**
>
> When cleaning, observe protection classes IP43 (instrumentation cabinet) and IP66 (operating panel)!

Instrumentation Cabinet

Proceed as follows for cleaning:

1. Switch off the device at the main switch and disconnect it from the power supply.

2. Wipe down the surfaces of the instrumentation cabinet with a damp, soft cloth or tissue.

3. If necessary, clean with a suitable (non-aggressive!) disinfectant.

Operating Panel

Proceed as follows for cleaning:

1. Switch off the device at the main switch and disconnect it from the power supply.

2. With the exception of the screen, wipe down the surfaces of the operating panel with a damp, soft cloth or tissue.

3. If necessary, clean with a suitable (non-aggressive!) disinfectant.

4. Wipe the screen with a cloth that is suitable for PC screens.

Disassembly and Disposal

9 Disassembly and Disposal

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

> ⓘ If the device is to be returned to the manufacturer for disassembly and disposal, a legally compliant declaration of decontamination is required for the safety of all parties involved and to comply with legal requirements (➥ Chapter 1.9 'Declaration of Decontamination' on page 14).

9.1 Disassembly

Prior to disassembly:

- Switch off the device and secure against reactivation.
- Physically disconnect the main energy supply from the device and wait for any components to fully discharge.
- Remove and dispose of all operating and auxiliary materials as well as remaining processing materials in an environmental acceptable manner.

Clean and disassemble component parts professionally with regard to any local regulations concerning employment and environmental protection. If possible, separate materials.

9.2 Disposal

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

- Scrap metals.
- Recycle plastic components.
- Sort and dispose of the remaining components according their material composition.

> ⚠ **WARNING**
>
> 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.

For disposal, the system units must be disassembled and dismantled into individual material groups. These materials must be disposed of according to the applicable national and local legislation. Local authorities or specialist disposal firms can provide information regarding environmentally acceptable disposal.

If no special arrangements have been made for return, Infors devices with the required declaration of decontamination can be sent back to the manufacturer for disposal.

Technical Data

10 Technical Data

10.1 Dimensions
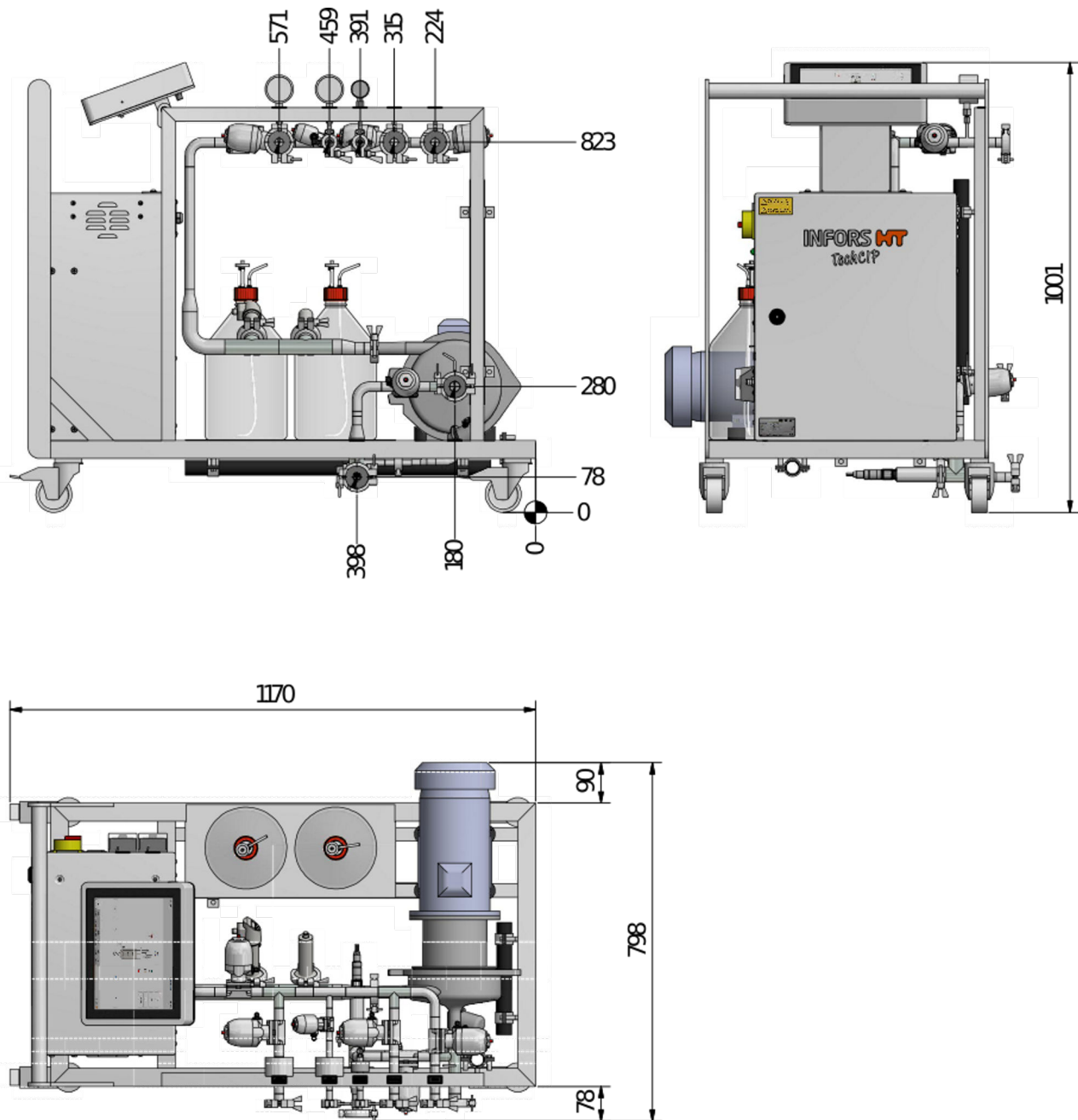
All dimensions in mm
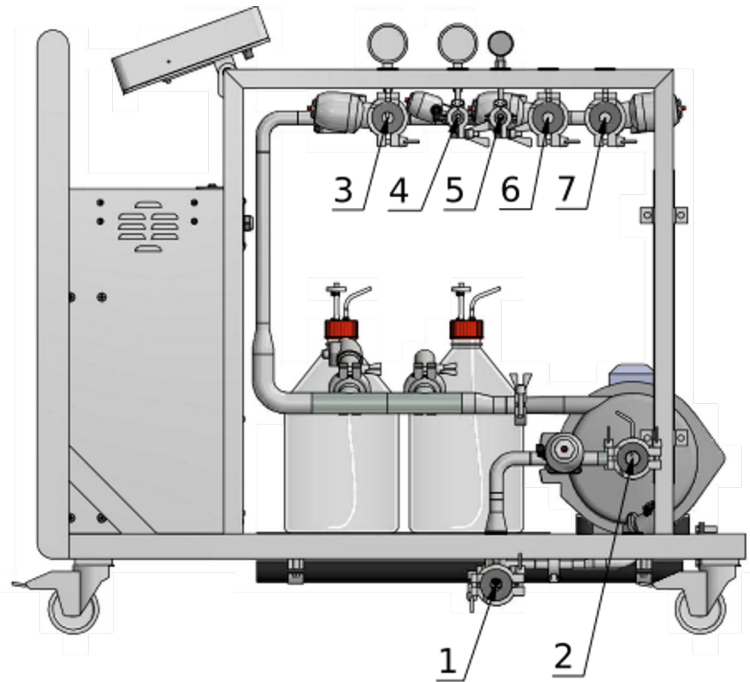
10.2 Connections and Connection Values

Connections Overview

Connection Values

Pos.	Connection	Connection type	Connection value
1	*Waste CIP* (waste water)	Tri-Clamp NW15	pressureless
3	*WFI in* (water for injection)	Tri-Clamp NW15	2.0 ± 0.2 bar
4	*Air in* (air for the CIP process)	Tri-Clamp NW08	2.0 ± 0.2 bar
5	*Instrument air* (instrument air, pressurised air for pilot valves)	Tri-Clamp NW08	6.0 ± 7.0 bar

Pos.	Connection	Connection type
2	*CIP in* (connection for bioreactor bottom valve)	Tri-Clamp NW20
6	*CIP out* (connection of CIP lance 1 + 2 bioreactor)	Tri-Clamp NW15
7	*CIP periphery* (connection for bioreactor inlet air + exit gas)	Tri-Clamp NW15

All Tri-Clamp connections as per DIN 32676 B (ISO1127) +A14 and DIN 32676 C (ASME-BPE 2009)

Electrical Connection Values

Data	Value	Unit
Voltage	230	V
Frequency	50	Hz
Max. rated current	16	A
Leakage current	3.5	mA

10.3   Specifications

10.3.1   Instrumentation Cabinet

Data	Value	Unit
Width	320	mm
Depth	450	mm
Height	550	mm
Protection type	IP43	
Material	1.4301	

10.3.2   Operating Panel

Data	Value
HMI	Colour touch screen 12"
Protection type	IP66

10.3.3   Pumps

Data	Value
Type	Peristaltic
Number	2 (*Acid, Base*)
Control	Digital

Data	Value	Unit
Speed (fixed rotation speed)	150	min^{-1}
Accuracy	± 5	min^{-1}

10.3.4   CIP Pump

Data	Value
Type	Stainless steel centrifugal pump
Model	GEA Hilge HYGIA I K KYY 25/25/1.5/2
Shaft seal	Simple mechanical seal

Data	Value	Unit
Max. quantity conveyed	4	m³/h
Conveying pressure	25	m FLS
Motor power	1.5	kW

10.3.5   Pressure Monitoring

Data	Value
Sensor type	Piezoresistive electronic pressure switch
Sensor model	Ceraphant PTP33B

Data	Value	Unit
Measurement range	0 to 4	bar

10.3.6   Fill Level Measurement

Data	Value
Sensor type	Limit switch for liquids
Sensor model	Liquiphant FTL33

Data	Value	Unit
Max. process pressure	25	bar
Process temperature range	-40 to +150	°C

10.3.7   Conductivity Measurement

Data	Value
Sensor type	Conducell 4USF ARC

Data	Value	Unit
Measurement range	1 to 300000	µS/cm
Accuracy at 1 to 100000 µS/cm	± 3	%
Accuracy at 100 to 300000 µS/cm	± 5	%

10.4   Operating Conditions

Data	Value	Unit
Ambient temperature	5 to 35	°C
Relative humidity, non-con-densing	20 to 90	%
Altitude operating location	Max. 2000	m.a.s.l
Pollution degree as per EN 61010-1	2	
Min. distance from walls, ceilings and other equipment	150	mm

The maximum distance between the mobile CIP unit and the bio-reactor to be cleaned is predefined by the length of the connecting hoses.