

Safety Instructions for Products and Equipment

Manufactured and delivered by Company

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1. Introduction

All information and instructions in the present **Safety Instruction** set have been compiled in consideration of current standards and guidelines, the state of technology and our many years of experience and knowledge.

Operating Instruction & Manual are separate documents to be found on company website for each product, equipment, and devices. The **Operating Instructions** provide you with all the information necessary to install and operate the products, equipment, and devices.

No guarantee is given for the information provided. Company reserves the right to make technical changes to the equipment or changes to this document without any prior notice. - Page 1 | 9

The present **Safety Instructions** informs the operator how to:

- operate the device according to safety requirements,
- maintain the device according to guidelines,
- clean the device according to guidelines,
- take appropriate measures should a fault occur.

The operator and laboratory responsible is urged to:

- Read both the present **Safety Instruction** set and the **Operating Instruction & Manual**, understand all issues and insure that all personnel are entrusted with the operation, maintenance, cleaning and troubleshooting of the device. This applies particularly to the Safety Instructions listed.
- Please further read the **Operating Instructions** carefully and completely before installing and use of products, equipment and devices from Company.
- These sets of instructions are part of the product. Keep any of such instruction in a safe and easily accessible place near the device's site of installation and operation.
- If any of the instructions should be lost or misplaced, operator is obliged to find replacement or download the latest version from Company website.
- Any guarantees and warranties shall apply only to manufacturing-related defects and malfunctions.
- The products, equipment and devices from Company is designed for general laboratory conditions and techniques.
- In addition to the **Safety Instruction** set and the **Operating Instruction**, follow all general and local regulations for accident prevention and environmental protection.

2. Safety Information

These instructions facilitate safe and efficient use of products and equipment from Company. The instructions are part of the information package and must always be kept near products and equipment and should be available for the personnel, operator at user site at any time.

2.1 Notes on using these Instructions

Before starting any tasks, personnel must have carefully read and understood these instructions. The basic pre-requisite for safe working is compliance with all the safety and handling instructions stated in this instruction. Furthermore, any and all local accident, hazard prevention regulations or general safety regulations that may apply to the scope of application of the products, equipment shall apply.

2.2 Explanation of Symbols and Expressions

Symbols for warning in instruction sets are:

- Danger of severe personal injury and property damage!
- Warning of potential physical injury, health risk or risk of property damage!
- Danger of personal injury and property damage!
- Warning of potential health risk or risk of property damage!
- Danger of material damage!
- Useful information and tips
- Note regarding device operation

2.3 Definitions

Reference is made to separate folders named:

- **Measures** - <http://cercell.com/support/measures/>

- **Glossary** - <http://cercell.com/support/glossary/>

3. Safety Instruction

This section gives an overview of all important aspects of safety for the protection of individuals and to ensure safe and trouble-free operation.

3.1 General Safety Instructions

- The product may only be set up, started or serviced after gaining familiarity with the appropriate **Operating Instruction & Manual's**.
- The products, equipment and device must only be used indoor.
- Use the products, equipment and device only for its intended purpose as described in Product Specification.
- The products, equipment and devices is not ATEX (ATmosphère EXplosive) certified. The products, equipment and devices may not be operated in potentially explosive atmospheres.
- During operation of the products, equipment and device, do not permit any work method that hinders the safety of the products, equipment and device.
- Always keep the working area of the unit clean and orderly, in order to avoid danger from dirt or scattered parts.
- Do not exceed the technical performance data specified for each products, equipment and device.
- Keep all safety precautions and danger, hazard descriptions at the products, equipment and devices in legible condition and replace the descriptions as needed.
- Operation as well as work on the products, equipment and devices must only be carried out by trained personnel.
- In case of malfunction, immediately stop the unit.
- Have the fault corrected by appropriately trained personnel.

3.2 Intended Use

The products and equipment is designed and intended for specific purpose as described. Each product may only be used with equipment and under operating conditions described in relevant documentation. Users must be qualified to handle the devices and be aware of the hazards potentially associated with the process. Some processes may require the workplace be equipped with additional safety features (such as protective clothing, eye glasses and gloves) or that precautions be otherwise taken to protect personnel and working environment. Generally all country and industry-specific statutory or otherwise mandatory laws and regulations apply. Safety and warning instructions given in this document only apply to the product or equipment or devices and supplement the rules and regulations the operator stipulates at the workplace for the respective process. The user is solely responsible for applications, which go beyond the intended use described here and for each individual product or equipment or device, which are not described in instructions sets. Company does not accept any liability beyond the intended usage.

Furthermore, individual restrictions and product or equipment or device specifications in the offer description from the manufacturer also found in the delivery contract and such warranty terms also apply. Intended use also means that all specifications in these instructions must be followed. Any use beyond the intended use is considered to be misuse.

3.3 Danger in case of misuse

Misuse of the system may lead to dangerous situations - so:

- Never operate the system in explosive atmospheres.
- Never incorporate flammable liquids and gases into the process.

- Never keep or store flammable or explosive materials near the system.
- Never bypass or manipulate the safety equipment or safety components.
- Never use operating media and process chemicals other than those specified in appropriate operating instructions.
- Never exceed the specific thresholds (temperature and pressure conditions) of the system.
- Never carry out unauthorized changes or other technical modifications to the system.
- Never use replacement parts other than those approved by the manufacturer.
- Never place conductors on the system.

3.4 Approved Operation and Processes

Risk of accidents may occur if the approved operating liquids and process chemicals are not used!

- If the approved operating liquids and process chemicals are not used properly and the specific instructions are not followed, severe accidents may occur.
- Only use liquids for cleaning which guarantee system material resistance.
- Only use operating liquids the manufacturer has approved for the system.
- Always follow the specified limits in these operating instructions for pressure, temperature, concentration and thaw point when using operating media.

Danger of material damage if material compatibility and specifications is not taken into account:

- If the material compatibility of the products, equipment or devices is not taken into account and unsuitable operating materials are used, such as acids and alkaline agents, the products, equipment may be subject to corrosion and damage.
- Only agents with a pH value of 6–8 are permitted in products, equipment or devices.
- To regulate the pH value, however, it may be necessary to use an alkaline agent with a higher pH value.
- Decontamination must not be carried out with alkaline agents.
- Always observe the information in the safety data sheets for the relevant process media.
- Always observe the specifications for pH value, water hardness and conductivity.
- Peristaltic pump hose are not allowed to run dry
- Products, equipment intended for being liquid filled and heated are not allowed to operate dry
- Never rotate impeller system without liquid in SUB, SUF dry
- Some product is designed as prototypes for single-use only and will be damaged during treatment with >80% ethanol solution or temperature above 50°C
- Sensor cables, fiber-optic cables, cables in general must not be autoclaved, irradiated, otherwise this can cause damage and have a negative effect on the process!

3.5 Basic Hazards

The following section covers the rest of the risks posed by the system when used as intended. Observe all safety information given here and in other sections of these instructions. This is the only way to reduce risk of personal injury and property damage and avoid dangerous situations.

Getting Started

All products and equipment must be assembled carefully and safely.

- Before every start-up, check the assembly and connections of all equipment. Safety equipment, e.g., the various sensor/mechanical safety valve must meet the specifications and be installed.
- Before every start-up check for water cooling leaks, check connections is correctly assembled in order to insure correct flow.

Risk of contamination when working on a non-decontaminated system! Working on a system that has not been decontaminated can lead to severe poisoning, infections or allergic reactions:

- Before any work, make sure that the system has been properly cleaned/decontaminated.
- Only carry out work if there is a decontamination declaration that has been filled out and signed by an authorized individual.

3.6 Operator Responsibilities

Organizational Measures on the Part of the Operator:

The operator must point out the hazards to which personnel and the working environment may be subject during the process, must provide the suitable safety equipment, and must publish the stipulated safety requirements.

- Only operating personnel qualified to run the process may be employed for working with the bioreactor; they must be aware of potential hazards, and be thoroughly familiar with the handling of all devices.
- Non-authorized persons must be prohibited from working with the company products, equipment, devices. If hazards are associated with the process (e.g., due to cultures or media or chemicals), the workplace must be labelled with suitable danger symbols, e.g., "BIOHAZARD" and it should be possible to cordon it off or quarantine it if the circumstances require.
- The workplace must be suitable for the process, e.g., resistant to acids, bases or media and must be easy to clean, decontaminate and disinfect if contaminated, e.g., by the culture.
- In general, operators must wear suitable personal protective equipment (e.g., work clothes, gloves, safety goggles as well as a face mask if appropriate).

Workplace Setup:

Workplace and supply connections in the laboratory must meet the requirements stipulated in the equipment specifications. All intended equipment must be complete and free of defects and flaws.

Risk of injury if energy supply lines are inadvertently activated (e.g., power supply, water supply, compressed air, gas inlet supplies). Energy supply lines must be blocked down or secured against inadvertent start-up whenever you:

- Connect or disconnect laboratory connections.
- Wish to remove the SUB, SUF, RUJ, SUP, PCS or peripheral devices in general.

Be alert and insure:

- Ensure that the laboratory supply voltage, water and gas supply match the specifications of each product, equipment.
- The workplace must be able to carry the weight of the product, equipment with all the intended peripheral devices. Observe the weight and the space requirements. Use suitable transportation aids when transporting the system to the place of installation and/or changing its location.
- Secure all laboratory or industrial connections carefully.
- Use only the equipment provided and approved. Never make any technical modifications, unless Company has expressly confirmed that this modification does not affect safe use.
- Remove any transport locks.
- Check all equipment carefully for damage. Use only flawless parts.

Danger of injury due to personnel being insufficiently qualified! If unqualified personnel work on

products, equipment or devices supplied by Company or enter the danger zone around the system, they risk severe injury and significant damage to property:

- Only allow qualified personnel to carry out work on the system.
- Keep unqualified personnel away from the danger zone.

3.7 Personnel Requirements at user site

Risk of danger of injury if personnel qualifications are insufficient!

Improper use can lead to significant personal injury and/or property damage. The device should be only operated by qualified and authorized personnel who have received safety instruction.

The laboratory responsible and the operator is responsible for the qualification of operating personnel.

- Make sure that those individuals who operate possible chiller are trained in the related work.
- The operators must be trained in the dangers involved with their tasks, as well as measures for their prevention, at regular intervals.
- Make sure all persons tasked with operating, installing and maintaining the device have read and understood the safety information and operating instructions.
- When using hazardous materials or materials that may be hazardous, the chiller may only be operated by persons completely familiar with these materials and the device.
- The staff must have knowledge in handling the (operating) materials used (safety instructions). These persons must be aware of all possible risks.

The following qualifications for personnel, operator performing work in different fields are given in these instructions:

Electrician at user site

Due to his or her technical education, knowledge, and experience, as well as knowledge of applicable standards and regulations, an authorised electrician is capable of carrying out work on electrical equipment and independently detecting and avoiding possible dangers. The electrician is specially trained for the operational site where he or she works and knows the relevant standards and regulations.

Technician at user-site

Due to his or her technical education, knowledge, and experience, as well as knowledge of applicable norms and regulations, a technician is capable of carrying out tasks assigned to him or her and of independently detecting and avoiding possible dangers.

Technicians must be able to provide evidence of training or multiple years of experience working as a chemist, laboratory technician or laboratory employee in the chemical, pharmaceutical or biotechnological industry. Technicians must also be able to provide evidence of training by the manufacturer of the system in its operation, and in the preparation and carrying out of planned processes.

Due to the components' high intrinsic weight, much of the work to be carried out requires a second specialist. If this is the case, this will be noted in the relevant instruction.

Company Service Personnel

Certain tasks may only be carried out by Company service personnel. Other individuals are not authorized to carry out specific work. Such as opening products, equipment, and devices. To have this work carried out, contact the Company service technician responsible for you.

Operator's Service Technicians

Certain work may also be carried out by the operator's service technicians, as described herein the operating instructions. These service technicians are trained and authorized, and are familiar with

the technical equipment and the system's processes and the potential dangers associated with its servicing and maintenance. Only those individuals who can be expected to carry out their work reliably are permitted as personnel. Personnel with impaired reaction times, for example due to drugs, alcohol, medication, etc., must not work on the system. The operator must also follow the age and occupation-specific regulations applicable on site in the selection of personnel.

4. Installation and Initial Start-up

The initial installation includes setting up the product, equipment and its connection. The following information summarizes the key aspects to be observed during the setup. They also apply to the re-installation at the workplace after a change of location or after temporary suspensions from use.

4.1 Checks Prior to Setup and Connection

Requirements Relating to Laboratory Connections and Energy Supply Lines. The following is required and/or must be ensured, among others:

- Electrical connections with proper voltage and proper ground and without impulse voltages or unallowable voltage fluctuations (protected with ground fault circuit interrupters or equivalent fault current protective devices or the likes),
- Electrical connections, supply voltage according to Manufacturer's Identification Label
- Cooling water without pressure surges, free of particulate matter and with allowable water hardness,
- Compressed air and other gases without pressure surges, and free of condensate and particulate matter,
- Equip all supply lines used for cooling water, compressed air and gases with suitable fittings for blocking or emergency shutoff.

Prior to installation at the installation location, energy and supply connections must be prepared and easily accessible, the energy sources must be dimensioned in accordance with the specifications for the respective product, equipment and be free of qualitative flaws. Information on this subject can be found in the manual for the specific product, equipment.

Risk of personal injury and property damage if the installation location does not meet the set requirements.

The table top or floor surface at the workplace must be able to hold the weight of the product, equipment.

The total weight of products, equipment depends on the customer's specific equipment, the connected peripheral devices and the weight of the possible medium, heating/cooling liquid at maximum filling. Setup surface and room height must be dimensioned in such a way that makes the product, equipment easily accessible for in-process operation, maintenance and service work. The space requirements also depend on the peripheral devices to be connected.

Risk of personal injury and property damage due to improper cabling and tubing! Incorrectly laid cables and tubes present a stumbling hazard and injury risk. Ripped out cables and tubes could permanently damage products, equipment and connected components. Ensure that all cables and tubes are laid so that they do not present a stumbling hazard.

4.2 Danger due to Electrical Power connection

The power supply (mains) in customer laboratory must meet the equipment specifications.

- The mains voltage and mains frequency must be compared with the specifications on the manufacturer's ID label on the products, equipment, devices.
- Do not switch on the device if the laboratory's mains voltage is incorrect.
- The laboratory's mains connections must be grounded, free from interference and splash-protected.
- Emergency shut-off equipment (ground fault circuit interrupters, power switch) must always be in perfect working order.
- The laboratory's power supply [Mains wall outlet] must be equipped with a protective grounding conductor.
- Do not use multiple socket outlets to connect the device to the laboratory's power supply (mains wall outlet).
- The power cables must have the correct plugs that match your laboratory AC outlet. Do not use any damaged mains cables, e.g. with broken insulation, and in particular if the wires are exposed.
- Do not attempt to repair any defective power cables or replace incorrect plugs. For this purpose, please be sure to contact a qualified service provider or technical customer service at Company.
- Check the electrical equipment of the device regularly for defects such as loose connections or damage to the insulation.
- In case of defects, turn the power supply off immediately and have the defects corrected by Company or authorized technicians.
- During repair work and cleaning, turn the power supply off and secure it against reactivation.
- Keep moisture away from parts under voltage, as it can lead to short circuits.
- Have the following tested by a qualified electrician according to the national regulations: electrical components, connection cables with plugs and extension and device connector cables with their sockets, given they are used.

Follow the information in the overall documentation.

4.3 Danger due to cold / hot surfaces and liquids

The water supply (mains) in end user, customer laboratory must meet the equipment specifications.

- The mains cooling water supply pressure must match the product requirements.
- Do not use unauthorised hoses for connecting products in cooling/heating loops. Use only armoured high temperature tolerance hoses.
- Skin burns and injuries are a potential hazard from heating elements and water heating loops.
- Prevent operator from being burned by hot water if water is used as the temperature controlling liquid may be hotter during start up and heating up a product.
- Wear safety gloves.
- Encase tubes and pipes in foam rubber for insulation and protection during handling.

Follow the information in the overall documentation.

4.4 Danger of injury from bursting products

The product, equipment and devices may generate overpressure if not operated correctly.

- Do not exceed the max operating pressures as described in the product, equipment, devices specification and the **Operating Instruction & Manual**.
- Insure overpressure safety valve is installed and operate properly on SUBs and SUFs according to product specification.
- Insure that venting filters work properly at their specified capacity and are kept free from media condensing in filters or adjacent hoses.
- Insure overpressure safety valve is installed and operate properly on Re-Usable-Jackets.
- Insure appropriate venting from safety valves to a safe reference like laboratory environment.

Follow the information in the overall documentation.

4.5 Danger of injury from leaked substances

If individual components or the product is damaged, gaseous and liquid materials may escape under high pressure and cause injury to eyes, skin, facilities, etc.

Follow the information in the overall documentation.

Therefore:

- Turn the device off and secure it against re-activation when working on pressurized components.
- Release the pressure from system sections and pressure lines to be opened before starting any repair work.
- Regularly check all lines, hoses and connections under pressure for leaks and externally detectable damage.

Follow the information in the overall documentation.

4.6 Risk of damage to products in liquid contact

If water is used as the temperature controlling liquid, it can freeze in the internal cooling water circuit of the chiller and damage the devices. For operating temperatures between +15 °C and +40 °C water specification according to the below recommendations. For lower temperatures, use appropriate amount of Glycol, given it is suitable for the application.

- Only use cooling liquid or water approved for the system supplied, according to the required specifications.
- Formation of scale deposits if water is measured to be hard
- Corrosion from distilled or demineralized water
- Faults resulting from contaminants or corrosion residues.

Malfunctions and damages arising from un-suitable cooling. Using water with a maximum hardness of 12 °dH minimizes scale build-up in the various loops and in the double wall of the SUB or SUF. If necessary, install a suitable pre-filter in the laboratory or feed line routed to the supply units.

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