



Biotech

Instructions for Use Part A: Hardware

USD3310

iCELLis® 500+ Bioreactor Control System Part Number: ICL500CSSSIP



Table of Contents

1.	Introduction	4
2.	Warnings	5
2.1	Hazard Icons	5
2.2	Hazard Level	6
2.3	Safety Messages	7
3.	Overview	10
3.1	iCELLis 500+ Single-Use Fixed-Bed Bioreactor	10
3.2	iCELLis 500+ Control System	11
4.	iCELLis 500+ Control System Environment Requirements	15
5.	Unpacking and Installing the iCELLis 500+ Control System	16
5.1	Unpacking	16
5.2	Moving and Positioning the iCELLis 500+ Control System	18
5.2.1	Unlocking Load Cells	18
5.2.2	Locking in Position and Levelling the System	19
5.3	Fitting High Speed Pumps on the iCELLis 500+ Control System	20
5.4	Fitting the Base Scale on the iCELLis 500+ Control System	21
5.5	Fitting the Tubing Holders on the iCELLis 500+ Control System	22
5.6	Fitting Communication and Sensor Cables to the iCELLis 500+ Control System	23
5.6.1	Connecting the Double Jacket Pressure Sensor Cable:	23
5.6.2	Connecting the Bioreactor Pressure Sensor Cable:	23
5.6.3	Connecting the T1 and T2 Temperature Probes:	25
5.6.4	Connecting Optical Fibers for pH and DO:	26
5.6.6	Connecting the Filter Heater:	28
5.6.7	Connecting the Bag Pre-Heater	30
5.7	Installation of the Temperature Control Unit (TCU)	31
5.8	iCELLis 500+ Control System Electrical Installation	35
5.8.1	Electrical Power Requirements	35
5.8.2	Power Connection and Powering ON	35
5.9	Fitting the Gas Supplies to the iCELLis 500+ Control System	36
6.	iCELLis 500+ Control System Specifications	38
6.1	General Specifications	38
6.2	Sensors and Actuators Specifications	41
6.3	Temperature Control Unit Specifications	42
7.	Cleaning	43
8.	Maintenance	44

9.	Disposal	45
10.	Technical Assistance	46
	Appendix A: Abbreviations and Symbols	47

1. Introduction

All information presented in this document has been verified according to applicable standards and guidelines at the time of writing. All legal and other binding regulations for personnel protection, accident prevention and protection of the environment applicable in the country of use of the system must be observed.

This instructions manual is intended to describe and explain the iCELLis 500+ bioreactor control system functions in standard configuration and general operating conditions. It provides information required for installation and operation of the system in these conditions. Read the manual carefully before operating the iCELLis 500+ bioreactor control system.

The Instructions for Use (IFU) must be read, understood and applied by all personnel authorized to operate, clean, service and maintain the system.



CAUTION!

The iCELLis 500+ control system must be used in accordance with instructions detailed in this manual. Utilization must be carried out only by authorized persons trained to the iCELLis 500+ control system operation.

Operation of the equipment may require other devices, instruments or safety equipment than the one described in this Instruction for Use. This document does not include detail about such conditions and related obligatory guidelines.

Warnings and safety messages are applicable only to iCELLis 500+ control system.



The figures, illustrations, parameters values and settings shown in this document are only examples and should not be used for a given application. Exact settings are provided through configuration documents or should be obtained empirically for a specific application.

This Instruction for Use has been released for the iCELLis 500+ control system hardware with the iCELLis 500+ software version 1.03.









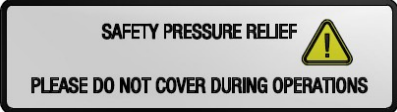
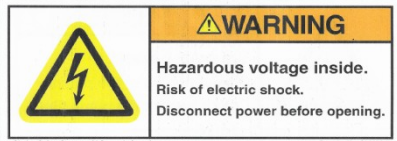
The iCELLis 500+ control system serial number can be found on the model plate located at the back of the equipment. The iCELLis 500+ software version can be found in Software HEADER after start-up of the controller.

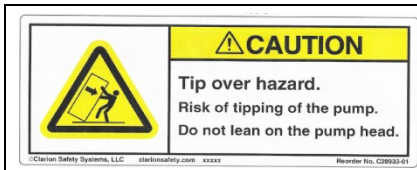
2. Warnings

2.1 Hazard Icons

The following icons are used in this Instruction for Use to point out hazards resulting from the utilization of the system described.

Documentation must be carefully assessed where these icons are present.

	<p>General icon for DANGER, WARNING, CAUTION or ALERT This symbol notifies general risk or specific procedures, which if not followed correctly, can result in injury of personnel or damage to equipment.</p>
	<p>Biological hazard DANGER icon This symbol notifies a biological hazard risk.</p>
	<p>Electrical Shock WARNING icon This symbol notifies a risk of electric shock.</p>
	<p>Crush WARNING icon This symbol notifies a risk of a crushing event.</p>
	<p>Hot Surface WARNING and CAUTION icon This symbol notifies a risk of burn.</p>
	<p>Magnetic field DANGER icon This symbol notifies a risk linked to magnetic fields.</p>
	<p>WARNING Risk of hand entanglement and crush These symbols notify a risk of hand or clothing entanglement. Red icon is displayed on peristaltic pumps.</p>
	<p>Information icon This symbol is used to highlight useful information and indicate that caution should be exercised while working on the system.</p>
	<p>CAUTION Do not cover during operations Safety pressure relief valve output. Do not cover during operations.</p>
	<p>WARNING Hazardous voltage inside Risk of electrical shock. Disconnect power before opening the doors.</p>



CAUTION Tip over hazard
Risk of tipping of the accessories pump. Do not lean on the pump head of the accessories pumps.



CAUTION Surface may be hot inside.
Risk of burn. Allow to cool before opening the bag pre-heater.



CAUTION Strong magnetic field.
Interaction with metallic objects may produce Pinch Hazards.
Persons with medical implants KEEP BACK 12 in. (30 cm) from the agitator shaft.

CAUTION
Wiring color differs from the NFPA 79 Standards.

ELECTRIC WIRE COLOR		
POWER CIRCUITS AC	ph	BLACK
	N	LIGHT BLUE (RAL 5015)
POWER CIRCUITS DC	+	BLACK
	0V	BLACK
DC CONTROL CIRCUITS 48V	+	WHITE
	0V	WHITE
DC CONTROL CIRCUITS 24V	+	DARK BLUE
	0V	DARK BLUE
DC CONTROL CIRCUITS 15V	+	PURPLE
	0V	PURPLE
AC CONTROL CIRCUITS	ph	RED
	N	RED
CIRCUITS SUPPLIED FROM AN EXTERNAL POWER SOURCE		ORANGE
PROTECTIVE EARTH (PE)		GREEN AND YELLOW

CAUTION wiring color differs from the NFPA 79 Standards.
The electric wire colour used in the iCELLis 500+ control system is listed on the label and conformed to the IEC 60445.
















2.2 Hazard Level















Hazard icons are used in combination with the following danger level indications:












DANGER!	Will lead to severe injury or death
WARNING!	May lead to severe injury or death
CAUTION!	May lead to light or moderate injury
ALERT!	May lead to material or data damage
IMPORTANT!	May lead to inconsistency in system utilization

Hazard or information icons may be supplemented with specific description or instructions.

2.3 Safety Messages

	DANGER! Risk of injury to personnel and/or damage to equipment! Before using the iCELLis 500+ control system, ensure you read and understand the safety instructions to prevent any damage to the equipment or any physical injury. Pall shall not be held responsible for any damage that may result from misuse. Misuse includes any use other than that designed for the iCELLis 500+ bioreactor and control system. Keep this guide handy for later reference. In the event you have additional questions, please contact Pall.
	DANGER! Risk of injury to personnel and/or damage to equipment! Use appropriate personal protective equipment (PPE) when moving and using the iCELLis 500+ control system.
	DANGER! Biological hazard! The biological hazard is a function of the process performed and is under the responsibility of the user. Appropriate safety risk analysis, depending on the biological material used, should be performed by the user. Appropriate personal protective equipment must be used.
	WARNING! Risk of injury to personnel and/or damage to equipment! The iCELLis 500+ control system must be operated by qualified people within a safe environment only. This equipment is expected to be installed in a controlled environment. Do not use the equipment in hazardous locations, such as Atmosphere Explosive (ATEX) Environmental operating conditions: 18 - 25 °C, 10 - 70 % relative humidity non-condensing. When not in use, the iCELLis 500+ control system must be stored in temperatures ranging from 4 °C - 40 °C, 80% maximum relative humidity non-condensing. Keep the iCELLis 500+ control system in a dry place.
	ALERT! Risk of damage to equipment! This equipment has been designed for indoor use only.
	DANGER! Risk of injury to personnel and/or damage to equipment! Before installing the iCELLis 500+ control system, ensure that the floor can support the weight of the system, the ancillary equipment and their content (such as cell culture media).
	ALERT! Risk of damage to equipment! Never use the equipment in a manner not specified by or clearly prohibited by the manufacturer. Such inappropriate use may impair the equipment's built-in protections and would void the warranty.
	ALERT! Risk of damage to equipment! Do not use the iCELLis 500+ control system in an incubator.
	ALERT! Risk of damage to equipment! Never position the equipment so that it is difficult to access the machine main power switches, gas inlet ports and emergency stop buttons. A minimum clearance of 650 mm around the system (front, rear, left and right sides) is needed.
	WARNING! Risk of injury to personnel and/or damage to equipment! Refer to the operating manual of the Temperature Control Unit (TCU) provided within the documentation of the iCELLis 500+ control system. Make sure you read and understand all instructions and safety precautions listed in the operating manual of the TCU before installing or operating your unit.
	WARNING! Risk of injury to personnel and/or damage to equipment! Place the TCU on an even surface with a base made of nonflammable material.
	WARNING! HOT/COLD surfaces! Risk of injury to personnel and/or damage to equipment! Always empty the bath of the TCU before moving the unit. Do not drain the bath fluid while it is hot! Check temperature of bath fluid prior to draining (e.g. by switching the unit on for a short moment).
	WARNING! Bended tubing! Risk of injury to personnel and/or damage to equipment! Avoid sharp bends in the fluid tubing of the TCU and maintain a sufficient distance from surrounding walls. Make sure that the tubing is securely attached.
	CAUTION! Risk of injury to personnel and/or damage to equipment! When the TCU, media pre-heater or the filter heater are active the surfaces and tubes can be hot. Therefore, exercise particular caution when handling.
	ALERT! Risk of damage to equipment! Do not disconnect the communication cable between the iCELLis 500+ control system and the TCU

	during operation.
	DANGER! Oxygen causes a fire/explosion risk! Users are responsible for performing their own safety assessment and obtaining expert advice on the design of any system used to supply gases to the iCELLis 500+ control system. RELEVANT ONLY WHEN USING OXYGEN: In the unlikely event of a tubing or connection failure, oxygen may build up in and around the iCELLis 500+ control system. A means of independently monitoring oxygen close to the equipment is highly recommended. The monitoring system should be set up to prevent oxygen levels from reaching 24% or limits recommended by local regulations. In the event of a rise in oxygen above this level, the supply should be immediately shut down. The iCELLis 500+ control system can deliver oxygen up to 7 L/min. Oxygen supply to the iCELLis 500+ control system is the user's responsibility.
	DANGER! Risk of asphyxiation! Carbon dioxide can cause asphyxiation. Ensure that the work space has adequate ventilation. Do not place the system in an enclosed area. The iCELLis 500+ control system can deliver carbon dioxide up to 1.5 L/min. Carbon dioxide supply to the iCELLis 500+ control system is the user's responsibility.
	DANGER! Risk of asphyxiation! Nitrogen can cause asphyxiation. Ensure that the work space has adequate ventilation. Do not place the system in an enclosed area. Note that the iCELLis 500+ control system can supply nitrogen up to 1.5 L/min. Nitrogen supply to the iCELLis 500+ control system is the user's responsibility.
	WARNING! Risk of injury to personnel and/or damage to equipment! Gases supplied to the iCELLis 500+ control system must be regulated to specified pressure (maximum 2.5 barg or 36.3 PSIG) and must be oil-free, dry and clean (medical grade). To prevent possible system component damage, do not exceed these recommendations. Each gas line should be supplied with an ON/OFF valve and an independent regulator.
	WARNING! Risk of injury to personnel and/or damage to equipment! User is responsible for performing assessment on the risks linked to liquids used in the iCELLis 500+ control system and bioreactor. Appropriate personal protective equipment must be used.
	WARNING! High voltage! Always make sure this equipment is properly earthed/grounded.
	WARNING! Risk of injury to personnel and/or damage to equipment! Only use the mains supply cord that is supplied with the iCELLis 500+ control system.
	WARNING! Risk of injury to personnel and/or damage to equipment! When the iCELLis 500+ control system is set to manual mode, it will not be controlled by the automation logic. Product damages or personal injuries may result!
	WARNING! Risk of injury to personnel and/or damage to equipment! Never spray liquid or allow ingress of fluid into the fans of the iCELLis 500+ control system.
	WARNING! Risk of injury to personnel and/or damage to equipment! Before each maintenance, cleaning or moving operation, turn the iCELLis 500+ control system OFF, unplug the system from the AC power, shut down the gas supply, disconnect gas lines, lock the loadcells, remove the bioreactor, remove the manifolds and all liquids.
	WARNING! Risk of injury to personnel and/or damage to equipment! In case of leak of liquid appropriate actions must be taken for user safety according to applicable procedures and national rules.
	WARNING! Risk of injury to personnel and/or damage to equipment! The crated iCELLis 500+ control system should always be lifted in the upright position. The hardware should only be lifted from a side. Before lifting, ensure that the lifting device forks pass all the way under the box section of the hardware.
	WARNING! Risk of injury to personnel and/or damage to equipment! The repositioning of the iCELLis 500+ control system must be done by two or more people due to the weight of the system.
	WARNING! Risk of injury to personnel and/or damage to equipment! Manipulation and repositioning of the bioreactor on and off the iCELLis 500+ control system docking station must be completed when the iCELLis 500+ bioreactor is completely empty and must be done by two people due to the weight of the bioreactor.

	WARNING! Risk of injury to personnel and/or damage to equipment! The positioning of the accessories pumps (optional FILL and DRAIN pumps) must be done by two people due to the weight of the pump.
	WARNING! Risk of injury to personnel and/or damage to equipment! Accessories pumps (optional FILL and DRAIN pumps) must be properly placed and stability of the pump must be checked before operation.
	CAUTION! Risk of entanglement and crush injury when using peristaltic pumps! Do not allow fingers or clothing to contact moving parts of the peristaltic pumps. Keep peristaltic pumps cover closed when pumps are operating. User must stop the peristaltic pumps before installing and removing tube from peristaltic pump heads.
	ALERT! Risk of damage to equipment! Only the iCELLis 500+ bioreactor provided by Pall should be used with the iCELLis 500+ control system.
	ALERT! Risk of damage to equipment! Never block the cooling fan outlets and cooling air inlet on the iCELLis 500+ control system when the iCELLis 500+ control system is powered.
	ALERT! Risk of damage to equipment! Only exhaust filter heater provided by Pall should be used with the iCELLis 500+ control system.
	ALERT! Risk of damage to equipment! The iCELLis 500+ control system should never be moved when there is liquid in the bioreactor.
	ALERT! Risk of damage to equipment! NEVER restrict flow of gas through the exhaust lines of the iCELLis 500+ bioreactor (gas out line).
	ALERT! Risk of damage to equipment! The iCELLis 500+ control system is equipped with load cells under the docking station for bioreactor weight measurement. Load cells must be secured using supplied locking plates during control system transport and handling in order to avoid damage. Locking plates must be removed prior to use of the system.
	WARNING! Magnetic field! Risk of injury to personnel! The iCELLis 500+ control system and iCELLis 500+ bioreactor contain strong magnetic elements. Persons with certain metallic, electronic, magnetic, mechanical implants, devices, or objects may not enter this area.
	ALERT! Risk of damage to equipment! Do not tilt the iCELLis 500+ bioreactor during the draining of the double jacket while it is on the control system. The load cells can be damaged.

3. Overview

The iCELLis 500 bioreactor platform is a high-cell density culture system designed for animal cell culture under large scale Good Manufacturing Practices (GMP) production. It consists of a single-use fixed-bed bioreactor and a docking station including controlling system with integrated measuring, agitation, temperature control and pumping elements to operate the bioreactor.

3.1 iCELLis 500+ Single-Use Fixed-Bed Bioreactor

The iCELLis 500+ bioreactor is fully single-use including its sensors. The bioreactor vessel contains a pre-packed fixed-bed made of Pall's proprietary iPack carriers designed for both suspension and adherent cells which grow entrapped in the fixed-bed. This matrix is made of medical grade polyethylene terephthalate (PET) microfibers.

The volume of the fixed-bed (number of carriers) varies depending on the bioreactor model but the outer shell (body) of the bioreactor does not change with the fixed-bed volume and offers a maximum working volume of ~74 L (Further media volume can be added through perfusion/ recirculation). Hence, the same docking and controlling station is used with all iCELLis 500+ bioreactors.

The volume in the bioreactor which the fixed-bed occupies varies from 5 to 25 L offering a cell adherence equivalent surface area between 66 to 500 m² respectively. A surface area of 500 m² is equivalent to ~3,000 roller bottles (1700 cm² each).

The main elements of the iCELLis 500+ bioreactor are:

- A body made of Polyethylene Terephthalate Glycol (PETG) parts, including a double-jacket for temperature control;
- A fixed-bed made of PET carriers;
- Different tubing and accessories such as integrated single use pH, DO, pressure and optional Biomass sensors (Figure 1).

The bioreactor is manufactured and assembled in accordance with ISO 14644-1 Class 8 cleanroom guidelines. Unless specifically marked otherwise, the bioreactor is delivered gamma-irradiated at a minimum of 25 kGy (range of 25 to 50 kGy). The product label includes a gamma exposure indicator (color change gamma-exposure indicator).

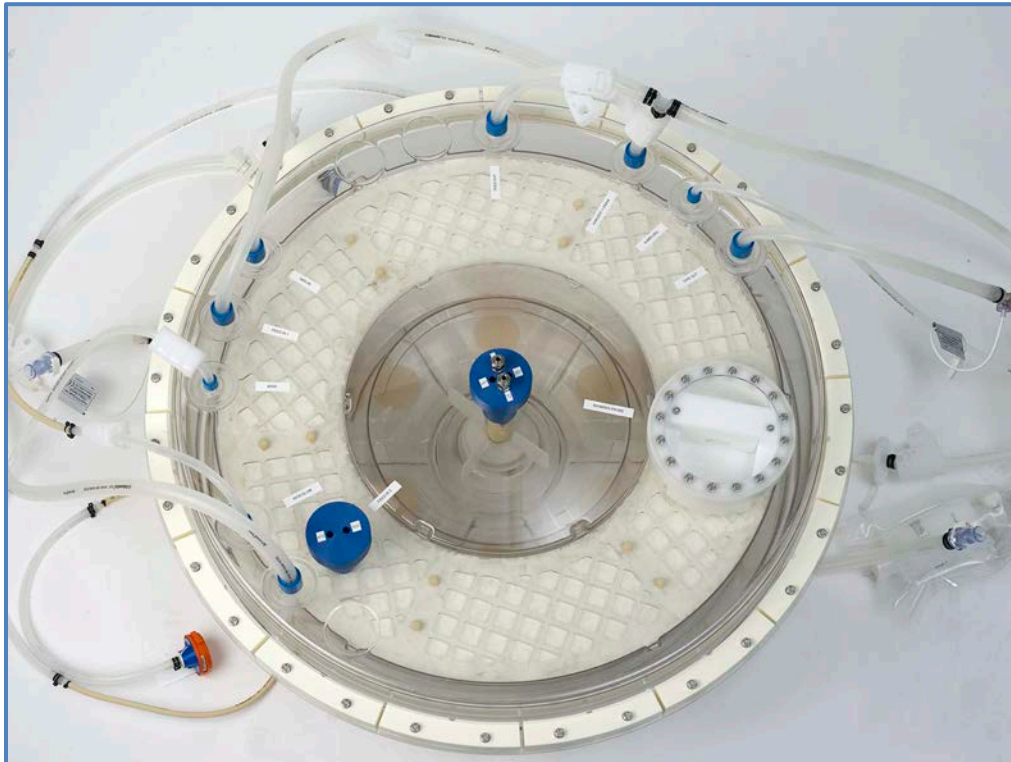


Figure 1: iCELLis 500+ bioreactor

3.2 iCELLis 500+ Control System

The iCELLis 500+ control system was specifically designed to operate, monitor and control the iCELLis 500+ bioreactors. The system body is composed of grade 304/316 L stainless steel and houses the following elements (Figure 2):

- A bottom assembly with controller PLC, agitation motor, electrical connection, media preheater, and the bioreactor docking station with load-cells; optionally two accessory peristaltic pumps can be added in dedicated compartments;
- A middle assembly with gas management block;
- A top assembly with pumps, probe connections, probe transmitters, electrical connections, emergency stop buttons and the touch screen panel;
- An external TCU for bioreactor temperature control.

The bioreactor is placed on the docking station, which contains the load-cells and a magnetic coupling for the agitation. When installed on the docking station, the bioreactor is directly under the sensor connections.

Process control is performed through a dedicated interface (iCELLis 500+ software) and can be accessed locally through the touch-screen panel or remotely. The iCELLis 500+ software has been developed specifically for iCELLis 500+ platform in order to make the equipment compatible with authorities' standard guidelines for electronic records and signatures in biopharmaceutical processes (21 CFR Part 11, Eudralex Annex 11).

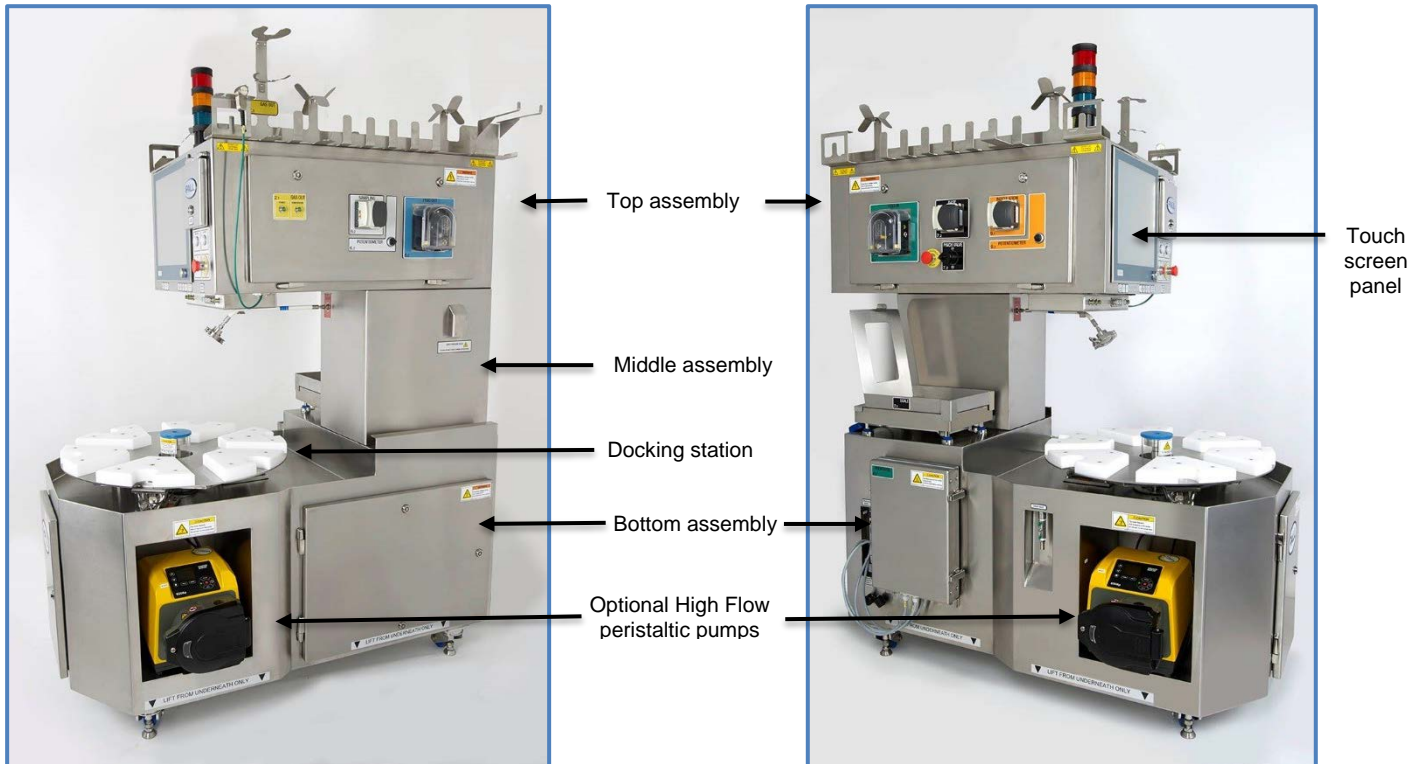


Figure 2: iCELLis 500+ control system

An overview of the iCELLis 500+ control system components in front, rear, right and left views are presented in Figure 3, Figure 4 and Figure 5.

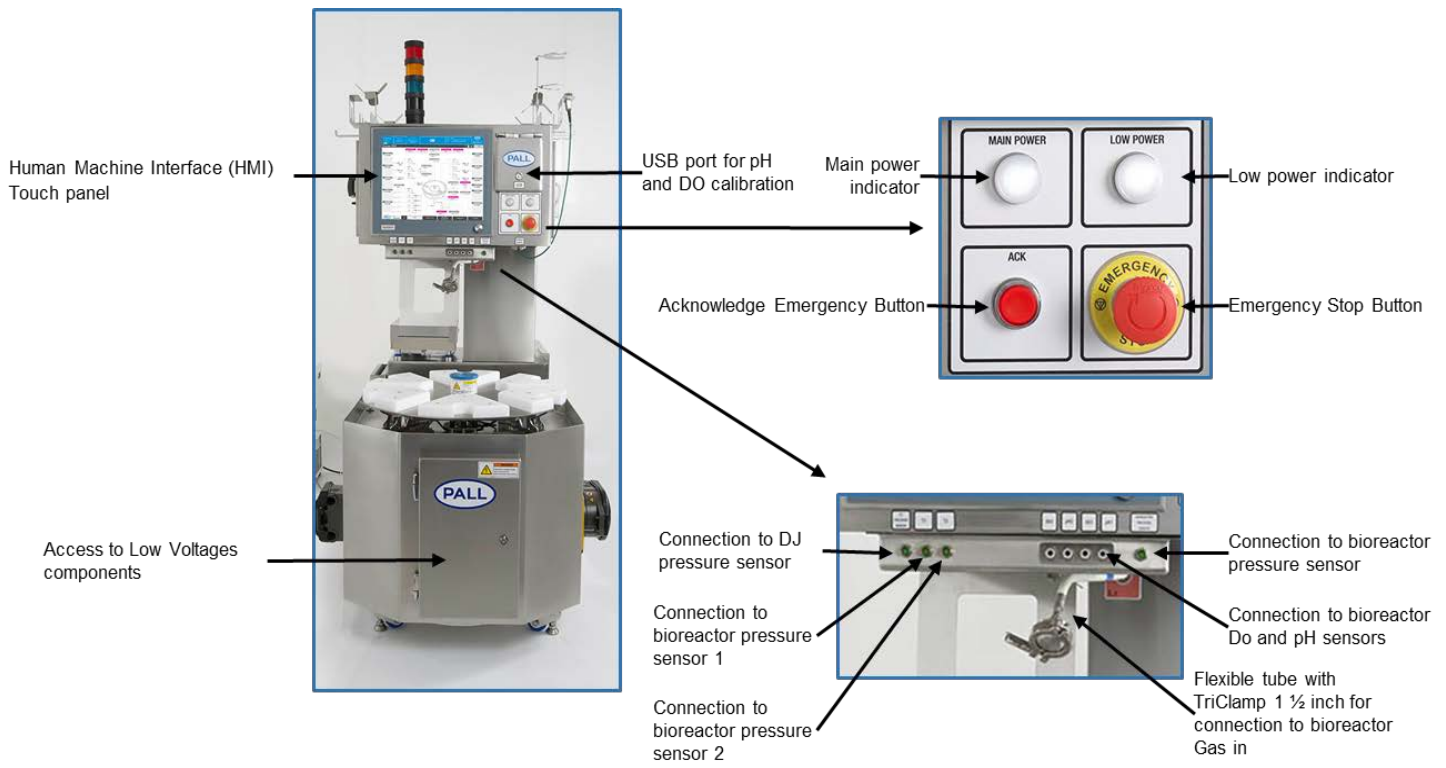


Figure 3: iCELLis 500+ control system front view

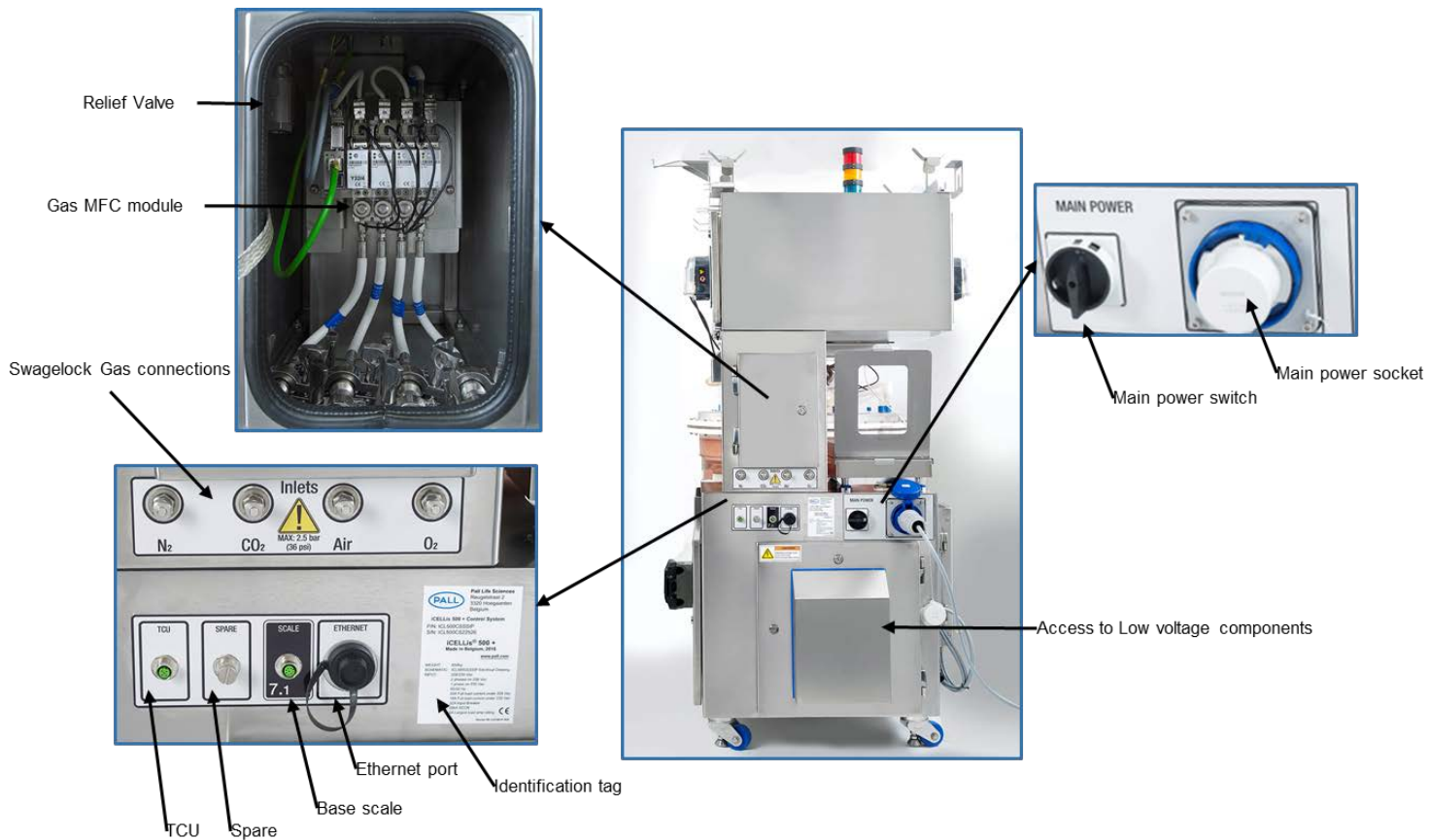


Figure 4: iCELLis 500+ control system rear view

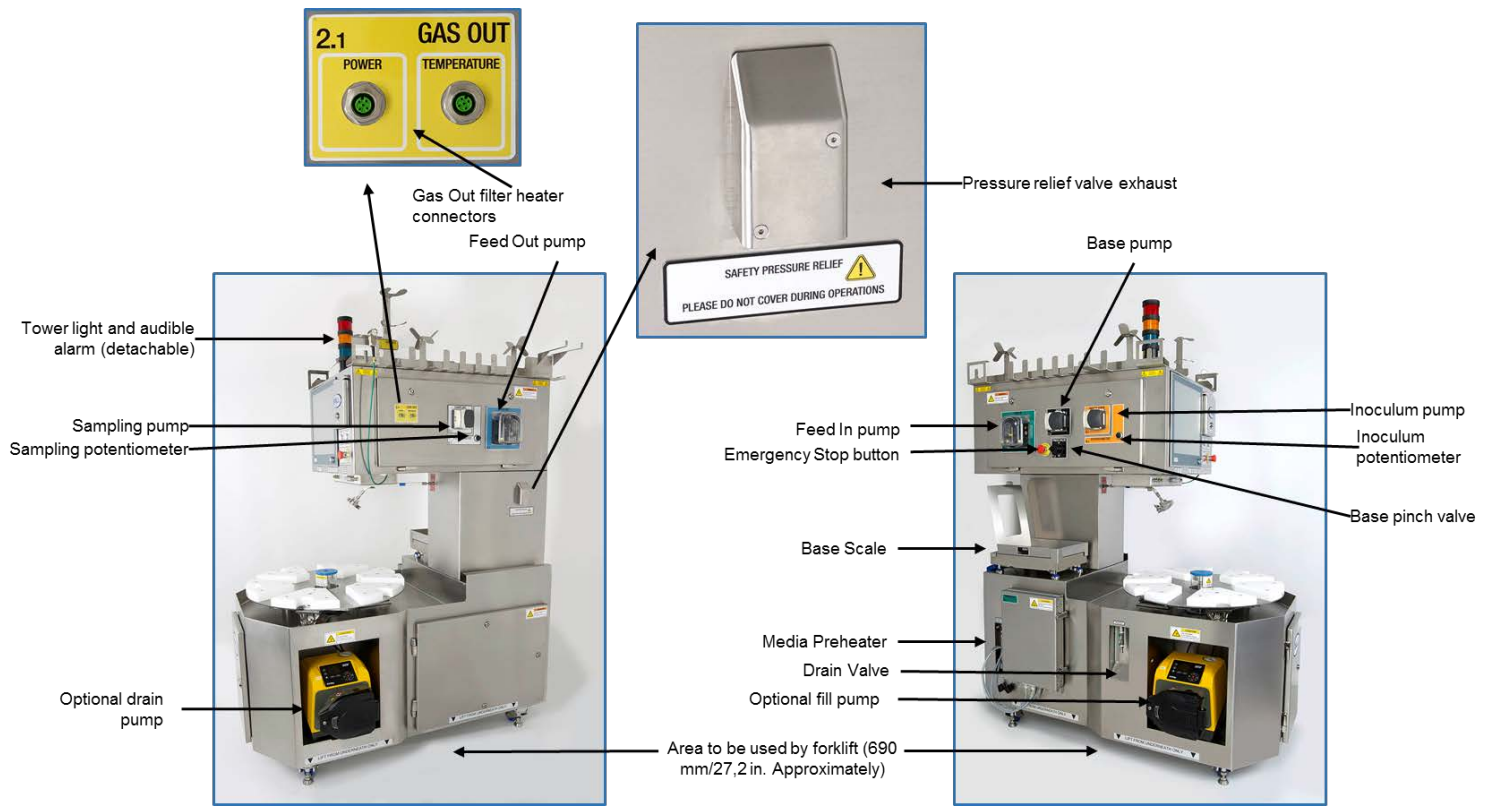


Figure 5: iCELLis 500+ control system right and left views

4. iCELLis 500+ Control System Environment Requirements



WARNING! Risk of injury to personnel and/or damage to equipment!

The iCELLis 500+ control system is not ATEX certified. The system may not be operated in potentially explosive atmosphere.



DANGER! Risk of injury to personnel and/or damage to equipment!

Before installing the iCELLis 500+ control system, verify that the floor can support the weight of the system, the ancillary equipment and their content (such as cell culture media).



ALERT! Risk of damage to equipment!

This equipment has been designed for indoor use only and a maximum ambient environmental temperature of 25 °C.

The dimensions and weight of the iCELLis 500+ control system can be found in Table 1 below.

Table 1: iCELLis 500+ control system dimensions and weight

Description	Dimensions and Weight
Height	1850 mm (excluding visual alarm and tubing holders) 2122 mm (with visual alarm and tubing holders)
Width	955 mm (excluding optional high flow pump) 1038 mm (with optional high flow pump)
Length	1609 mm
Dry Weight (without bioreactor)	650 kg
Maximum weight when loaded (with bioreactor full of media and double jacket full of water)	< 850 kg

Environmental working conditions of the iCELLis 500+ control system are detailed in Table 2 below.

Table 2: iCELLis 500+ control system environmental working conditions

Description	Environmental Working Conditions
Environment condition	Indoor use only
Maximum Altitude	2000 m
Ambient operating temperature	18 °C to 25 °C
Relative operating humidity	10 - 70%, non-condensing
Pollution degree	2
IP rating	55

The work area where the iCELLis 500+ control system is installed and operated must be leveled and be able to accommodate the footprint and weight of the iCELLis 500+ control system with a 650 mm minimum clearance on each side of the system to enable access to the controller buttons (such as emergency stop buttons) and other inlets/sockets.

5. Unpacking and Installing the iCELLis 500+ Control System

The required materials for unpacking and installing the iCELLis 500+ control system are detailed below:

- Forklift with minimum fork length of 1.4 m capable of lifting 1.320 kg at the full length of the forks.
- Stepladder, scissors, spirit level, spanner (wrench):13 and 24 mm, adjustable spanner: jaw capacity 25 - 26 mm, Metric hex keys: 4 mm, 5 mm and 6 mm, small flat screw driver

5.1 Unpacking



WARNING! Risk of injury to personnel and/or damage to equipment!

The crated iCELLis 500+ control system should always be lifted in the upright position. Once outside the crate, the hardware should only be lifted from the side. Before lifting, ensure that the lifting device forks pass all the way under the box section of the hardware.



ALERT! Risk of damage to equipment!

Before placing the iCELLis 500+ control system on the floor, be sure the floor can support the weight of the system.



ALERT! Risk of injury to personnel and/or damage to equipment!

Never lift the iCELLis 500+ control system by the top.

The iCELLis 500+ control system is shipped within 2 wooden crates with the following dimensions and weight:

Table 3: Weight and dimensions of iCELLis 500+ control system crates

	iCELLis 500+ Control System	Accessories and Documentation
Crate weight	~850 kg	~300 kg
Crate dimensions (H x W x L)	2135 x 1120 x 1760 mm	1800 x 800 x 1200 mm

Inspect the crate to ensure it has not been damaged, also check the 'TIP N TELL' and Shock indicator (if applicable) located on the side of the crate for signs that the crate has been tipped or mishandled.

It is recommended that two persons uncrate the iCELLis 500+ control system together. The four sides, top and bottom sections of the crates are held together using the fixings shown in Figure 6b.

To uncrate: Remove one of the larger side panel then remove the top panel of the crate and finish with the remaining vertical panels. Remove the first layer of plastic wrap, then the wooden support for the top assembly and the second wrap (Figure 6 f-h). Proceed similarly with accessories and documentations crate (Figure 6i).

Lift the iCELLis 500+ control system from the base of the box using a forklift at the lifting points on the side of the unit (Figure 6h). Ensure the forks are positioned under the controller framework prior to lifting. Lifting in any other way may cause damage to the hardware. Once the iCELLis 500+ control system has been lifted move the crate base and place the iCELLis 500+ control system on the floor.

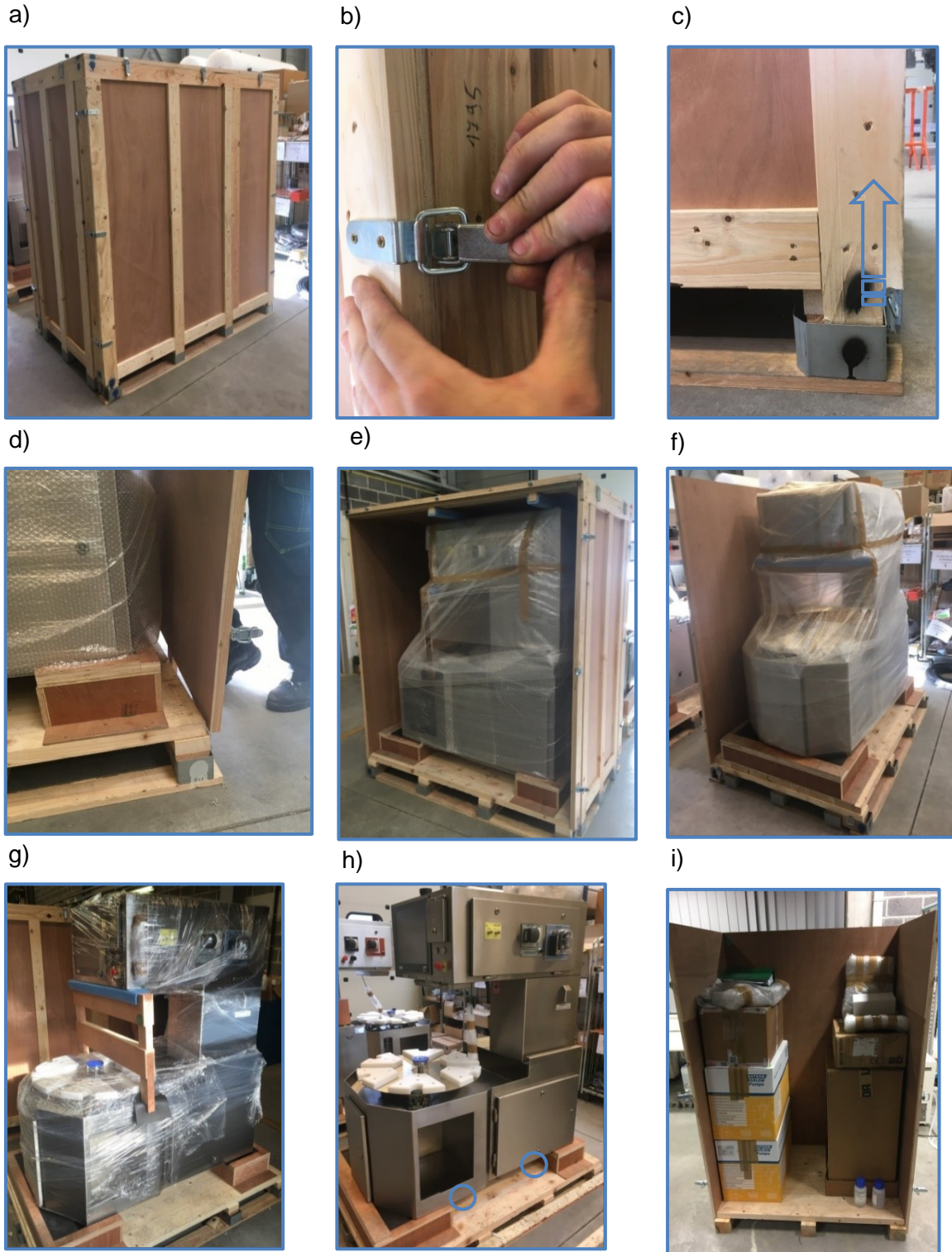


Figure 6: Uncrating the iCELLis 500+ control system – a) Crated unit, b) Removing crate fixing clips, c) Lifting side panel, d) Removing side panel, e) Side panel removed, f) Unit with double plastic wrap, g) Unit with external wrap removed, h) Unit unwrapped and lifting points (blue), i) Crate for accessories and documentation.

5.2 Moving and Positioning the iCELLis 500+ Control System



WARNING! Risk of injury to personnel and/or damage to equipment!

Manipulation and repositioning of iCELLis 500+ control system must be completed when the iCELLis 500+ bioreactor is completely empty and must be done by two or more persons due to the weight of the bioreactor.



DANGER! Risk of injury to personnel and/or damage to equipment!

Before installing the iCELLis 500+ control system, verify that the floor can support the weight of the system, the ancillary equipment and their content (such as cell culture media).



WARNING! Risk of injury to personnel and/or damage to equipment!

Before each **moving operation**, turn the iCELLis 500+ control system OFF, unplug the system from the AC power, shut down gas supply, disconnect gas lines, remove the bioreactor, remove the manifolds and all liquids.



WARNING! Risk of injury to personnel and/or damage to equipment!

The iCELLis 500+ control system must stand on its feet. Feet must be locked and leveled prior to powering the unit.

The iCELLis 500+ control system can be moved on its castors. Only the bottom assembly must be used to push or pull the unit. Do not push or pull from the docking station. Please do not move the equipment in any other way than instructed.

5.2.1 Unlocking Load Cells



ALERT! Risk of damage to equipment!

The iCELLis 500+ control system is equipped with load cells under the docking station for bioreactor weight measurement. Load cells must be secured using the supplied locking plates during control system transport and handling to avoid damage.

Locking plates must be removed prior to use of the system.



ALERT! Risk of damage to equipment!

Do not tilt the iCELLis 500+ bioreactor on the docking station during draining of the double jacket. Load cells can be damaged.



Please do not discard locking plates and store them in a safe place to be able to lock the load cells during future transport and handling of the iCELLis 500+ control system.

The iCELLis 500+ control system is equipped with 3 load cells which are locked during transport (Figure 7a).

Remove the locking plate for each load cell after the control system has been installed at its final location. Unscrew the Anti-Lift bolt with a 13 mm spanner and remove the Checking Sleeve (Figure 7b). Remove the Centering Spacer and the Locking Plate (Figure 7c). Place back the Checking Sleeve and the Anti-Lift Bolt (Figure 7d).

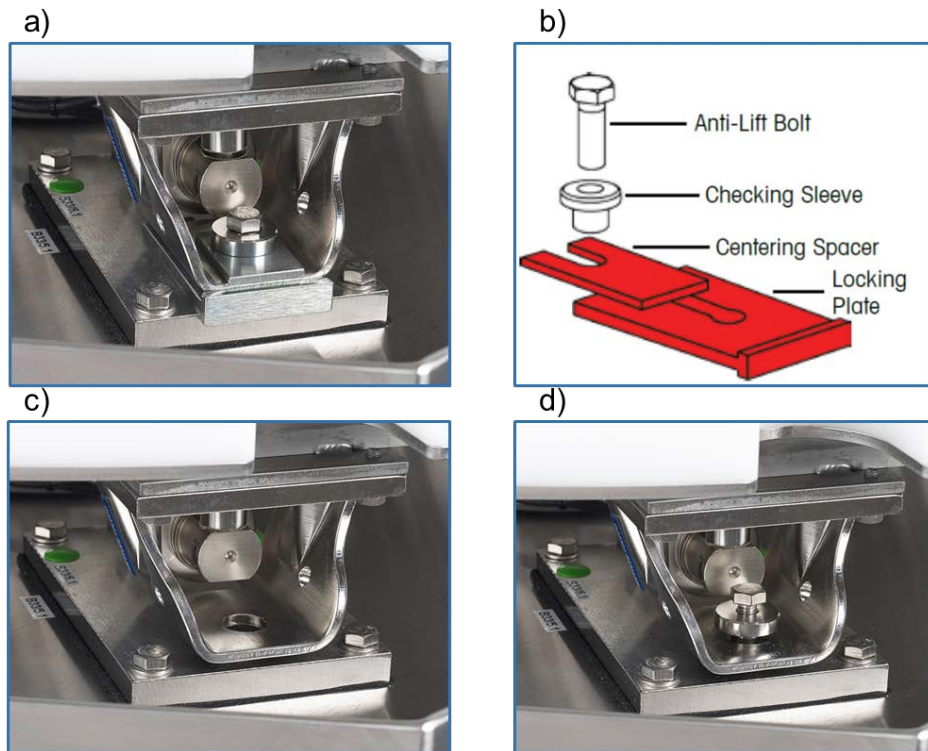


Figure 7: Load cell locking plate removal at system reception: a) Load cell with locking plate in place, b) Locking plate and fixation elements, c) Locking plate and bolts removed, d) Checking sleeve and anti-lift bolt in place.

5.2.2 Locking in Position and Levelling the System

Once the iCELLis 500+ control system is in its required position the wheels should be turned and feet lowered to lock the casters (Figure 8). When performing this step, a spirit level should be used and placed on the bioreactor docking station to ensure the hardware is leveled before use. When the iCELLis 500+ control system is leveled, lock the feet by turning the locking bolt on the caster. The feet should always be raised prior to moving the iCELLis 500+ control system.

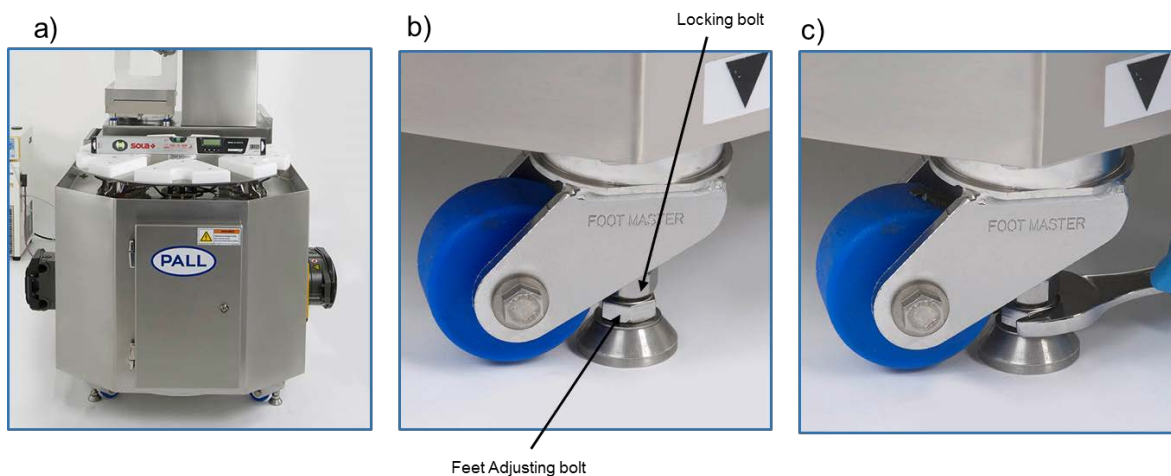


Figure 8: Positioning the iCELLis 500+ control system: a) level placed on docking station, b) and c) Wheel turned and feet lowered to lock casters.

5.3 Fitting High Speed Pumps on the iCELLis 500+ Control System



WARNING! Risk of injury to personnel and/or damage to equipment!

The positioning of the high-speed pumps must be done by two people due to the weight of the pumps.



ALERT! Risk of damage to equipment!

Always check the position and stability of the accessories pump before operation.



WARNING! Risk of injury to personnel and/or damage to equipment!

Before installing the accessories pump, turn the iCELLis 500+ control system OFF, unplug the system from the AC power, shut down gas supply, disconnect gas lines, remove the bioreactor, remove the manifolds and all liquids.

The high-speed pumps are packed in the crate for accessories and documentation. Unpack each high speed pump, and install the pump in its compartment (Figure 9a) prior to connecting to the iCELLis 500+ control system as per the Figure 7b. Connect the power cable (Figure 9c) and the communication cable (Figure 9d) to the iCELLis 500+ control system. Power to the pumps is supplied by the Control system.

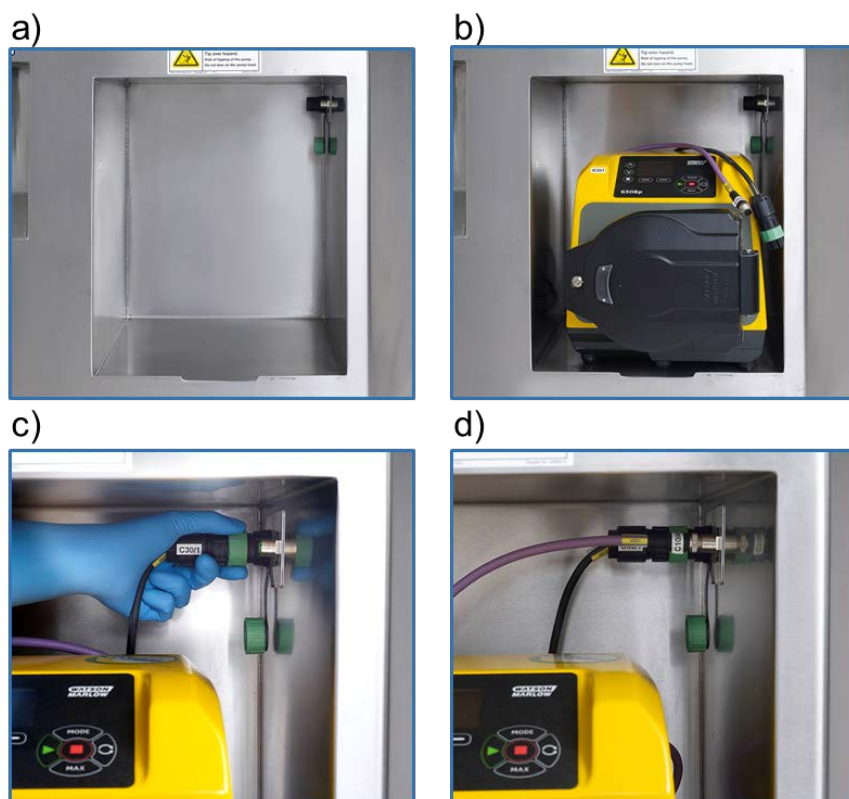


Figure 9: Placing and connecting High Speed pump: a) High speed pump compartment, b) High speed pump in compartment, c) Connection of power plug, d) Connection of communication port.

5.4 Fitting the Base Scale on the iCELLis 500+ Control System

The Base scale is packed in the crate for accessories and documentation. Unpack the Base scale and follow the procedure below to install and connect it to the iCELLis 500+ control system. Install the Base scale on the iCELLis 500+ control system as per Figure 10a-b. Connect the base scale at the back of the iCELLis 500+ control system to the 'scale' connector (Figure 10c). Place the Base tray on the scale (Figure 10d). Level the scale by turning the blue feet of the base scale. When the scale is leveled the bubble shall be in the center of the bubble indicator of the scale (Figure 10e).

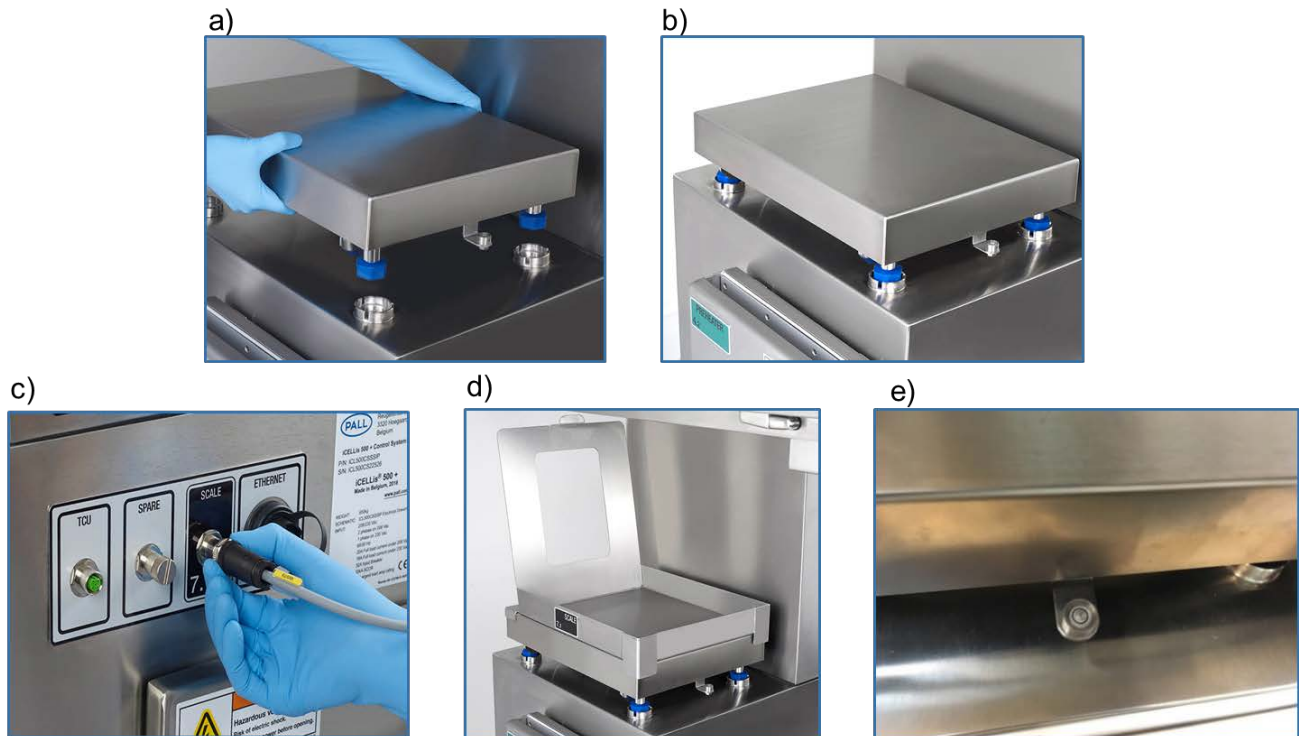


Figure 10: Installation of Base weight scale – a) Fitting Base scale in dedicated foot slots, b) Base scale in place, c) Connection of communication port, d) Base tray placed on Base scale, e) Base scale level bubble.

5.5 Fitting the Tubing Holders on the iCELLis 500+ Control System

The tubing holders are packed in the crate for accessories and documentation. The content of tubing holder pack is described in Table 4 below.

Table 4: Tubing holders pack items and description (The item number is used in Figure 11)

Item number	Description	Quantity
1	Seal washer – M16	4
2	Left tube holding channel - 2	1
3	Left tube holding channel assembly	1
4	Hex drive button head screwed in 7380 Stainless steel A2 M16 x 30 mm	4
5	Right tube holding channel assembly	1
6	Right tube holding channel - 2	1

Unpack the tubing holders and install all items on the iCELLis 500+ control system following below drawing.



Figure 11: Assembly position of tubing holders items on iCELLis 500+ control system
(the item number corresponds to Table 4)

5.6 Fitting Communication and Sensor Cables to the iCELLis 500+ Control System



ALERT! Risk of damage to equipment!
All cables should be hand-tightened (no tools).

5.6.1 Connecting the Double Jacket Pressure Sensor Cable:

The double jacket pressure sensor cable is packed in the crate of the accessories and documentation.



Figure 12: Double jacket pressure sensor cable

Connect the cable to the connector labeled 'DJ PRESSURE SENSOR' located on the front of the iCELLis 500+ control system (Figure 13a). Secure the connector by turning the metallic part of the connector (Figure 13b).

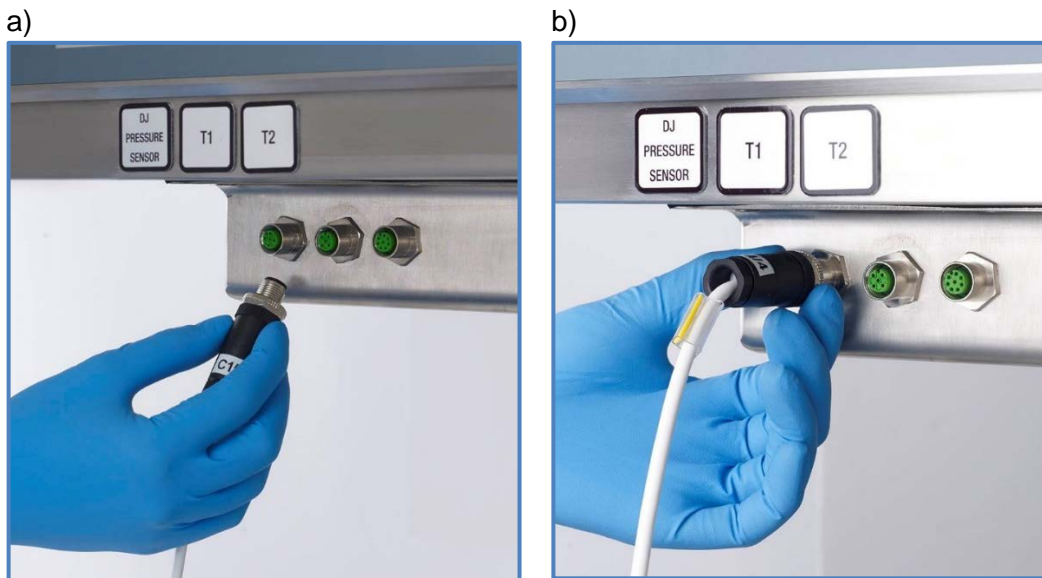


Figure 13: Double jacket pressure sensor cable connection – a) Cable of the pressure sensor being connected, b) Secured connection.

5.6.2 Connecting the Bioreactor Pressure Sensor Cable:

The bioreactor pressure sensor cable is packed in the crate of the accessories and documentation.



Figure 14: Bioreactor pressure sensor cable

Connect the cable to the connector labeled 'BIOREACTOR PRESSURE SENSOR' located on the front of the iCELLis 500+ control system (Figure 15a). Secure the connector by turning the metallic part of the connector (Figure 15b).

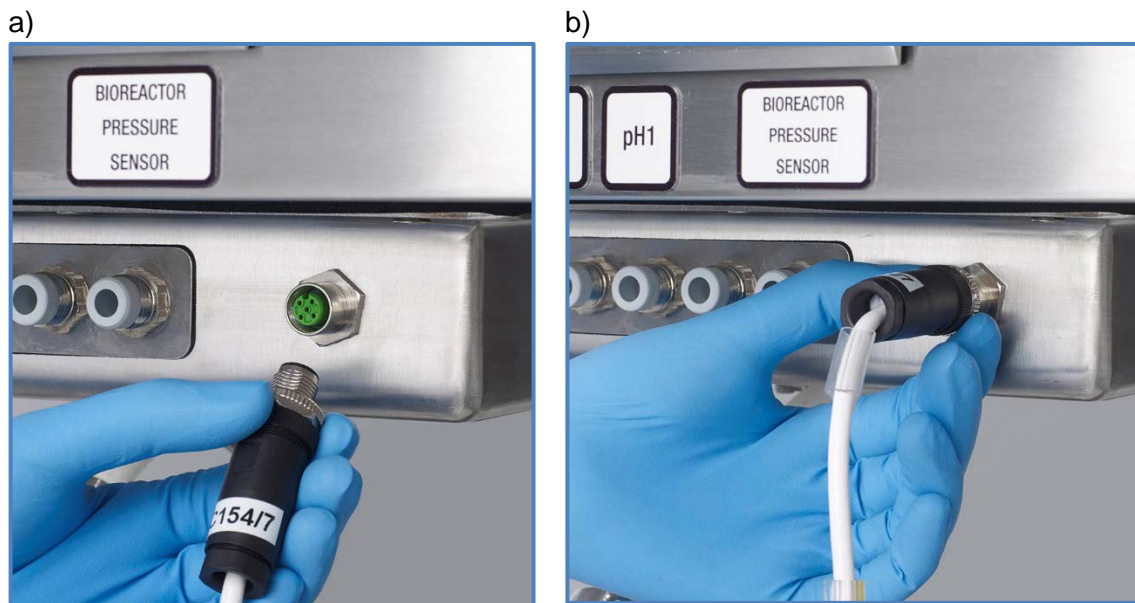


Figure 15. Bioreactor pressure sensor cable connection – a) Cable of the pressure sensor being connected, b) Secured connection.

5.6.3 Connecting the T1 and T2 Temperature Probes:

The T1 (grey cable) and T2 (white cable) temperature probes are packed in the crate of the accessories and documentation.

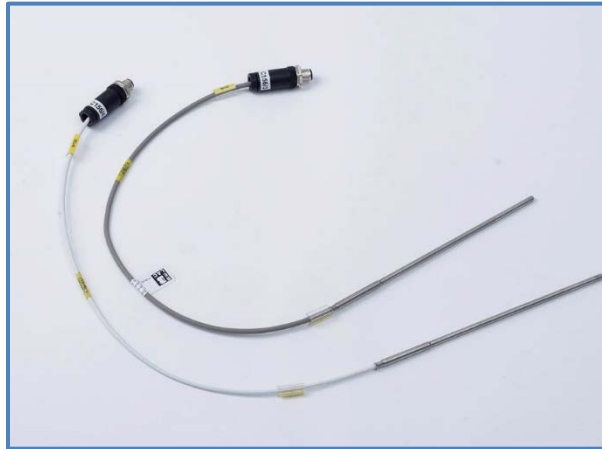


Figure 16: T1 (grey cable) and T2 (white cable) temperature probe

Connect the T1 temperature probe cable to the connector labeled 'T1' located on the front of the iCELLis 500+ control system (Figure 17a). Secure the connector by turning the metallic part of the connector (Figure 17b). Repeat steps to connect the T2 temperature probe to the connector labeled 'T2' (Figure 17c-d).

a)



b)



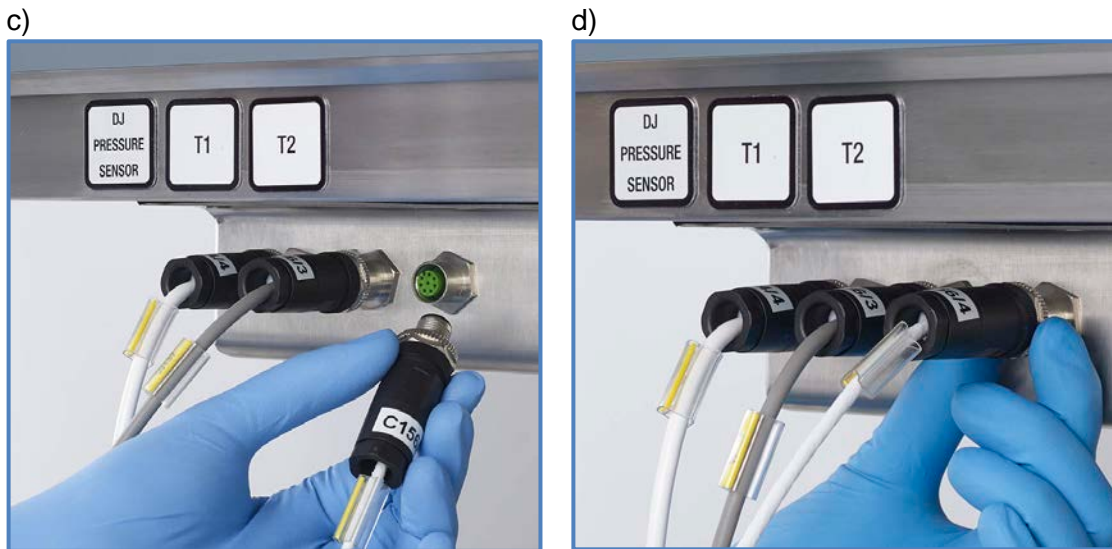


Figure 17: T1 and T2 temperature probes connection – a) Connect T1 temperature probe, b) Secured T1 connection, c) Connect T2 temperature probe, d) Secured T2 connection.

5.6.4 Connecting Optical Fibers for pH and DO:



ALERT! Risk of damage to equipment!
Take care not to bend the optical fibers.

The optical fibers for DO and pH readings before (DO1 and pH1, short ones) and after (DO2 and pH2, long ones) the packed-bed are packed in the crate of the accessories and documentation.



Figure 18: Optical fibers before (short) and after (long) fix bed

Connect the optical fibers after fix bed (long ones) to the optical connectors 'pH2' and 'DO2' located on the front of the iCELLis 500+ control system (Figure 19a-b-d). Secure the connector by turning the metallic part of the connector (Figure 19c). Repeat these steps to connect the optical fibers before fix bed (short ones) to the optical connectors 'pH1' and 'DO1' (Figure 19e).

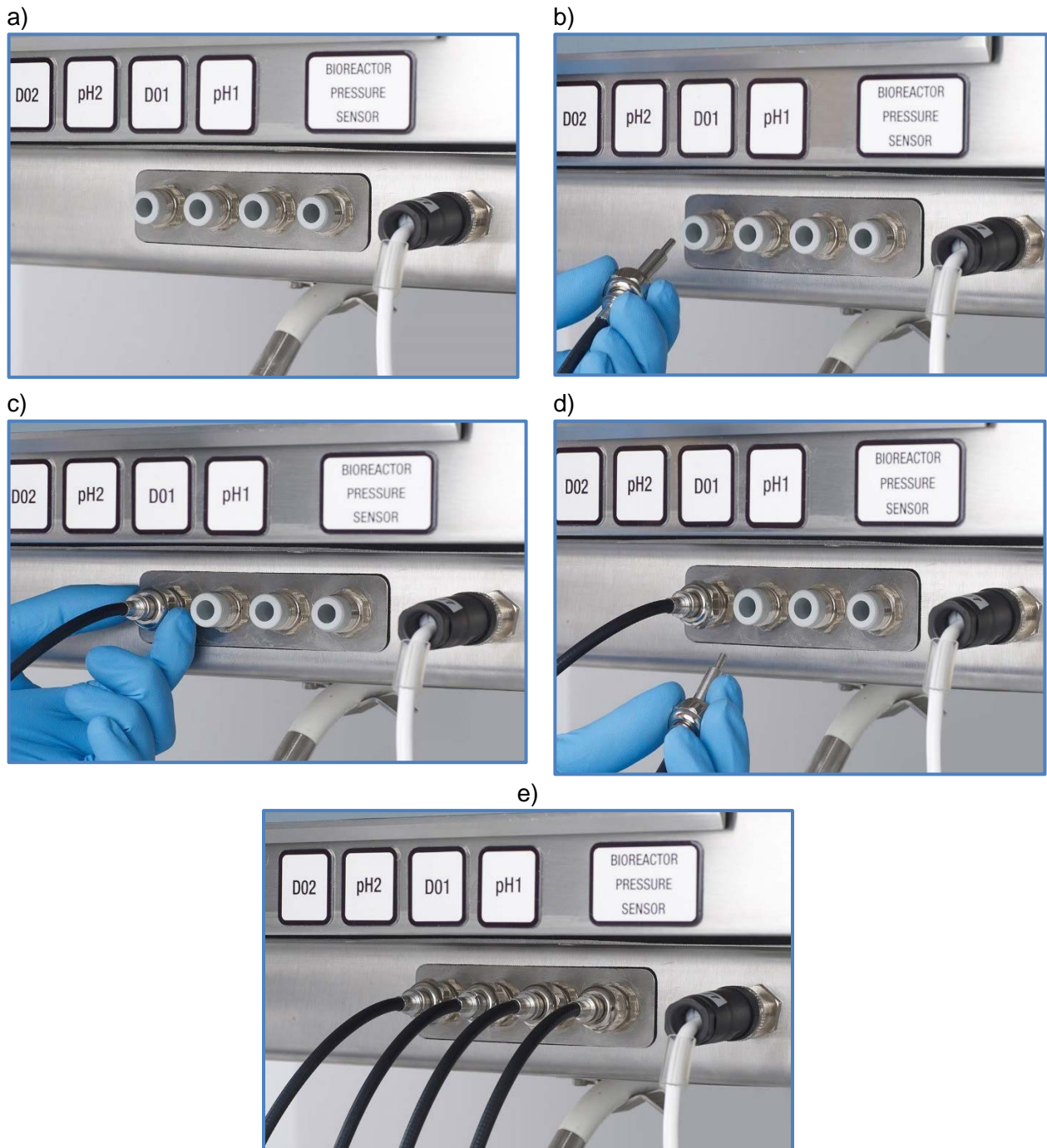


Figure 19: Connection of optical fibers before and after fixed-bed – a) Optical connectors, b) Connection to the DO2 connector, c) Secured connection, d) Connection to the pH2 connector, e) All optical fibers connected.

5.6.6 Connecting the Filter Heater:

The filter heater is packed in the crate of the accessories and documentation.



Figure 20: Filter heater

Connect the power connector of the filter heater to the connector labeled 'POWER' on the right side of the iCELLis 500+ control system (Figure 21a and b). Secure the connector by turning the metallic part of the connector (Figure 21c). Connect the temperature sensor connector to the connector labeled 'TEMPERATURE' on the right side of the iCELLis 500+ control system (Figure 21d and e).

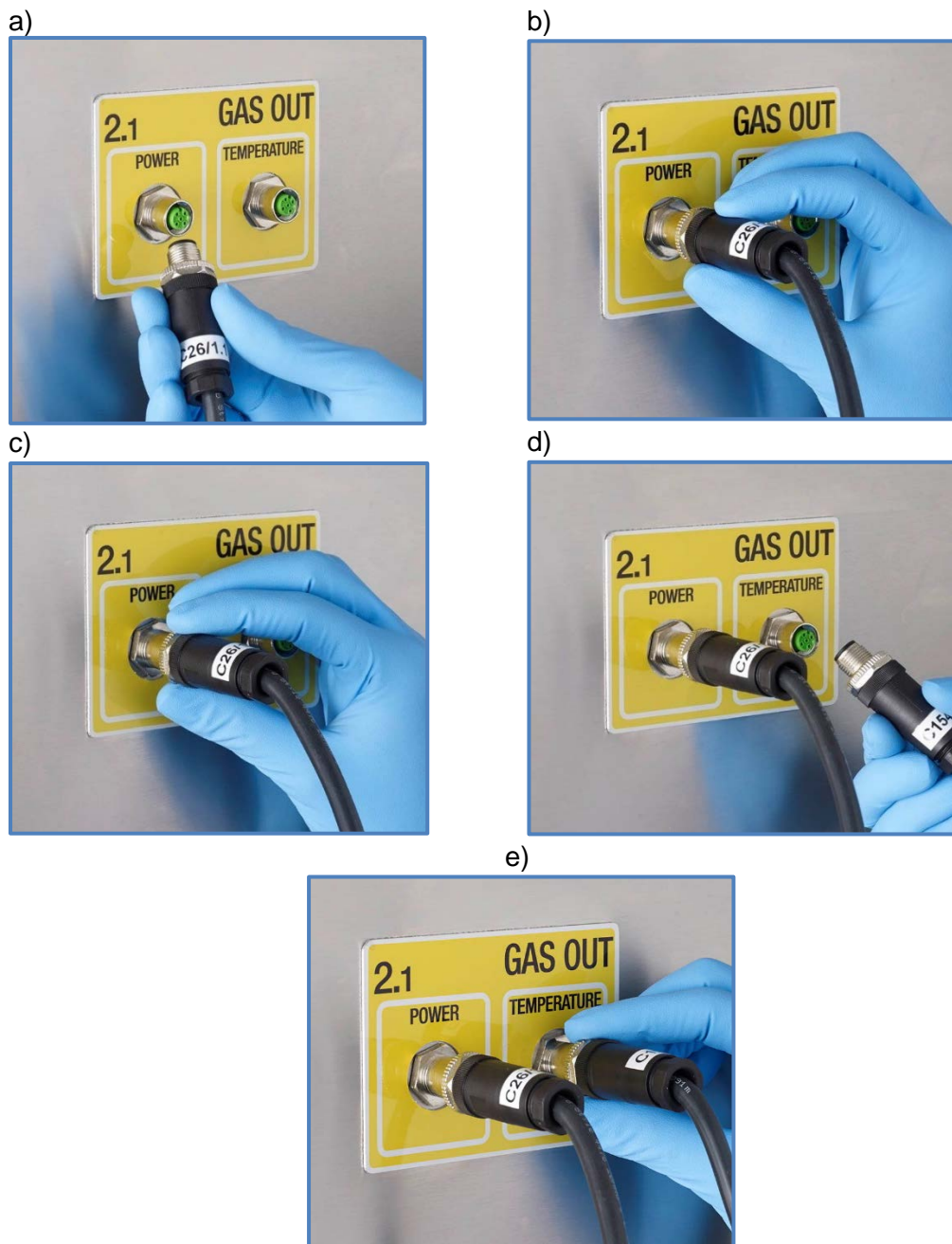


Figure 21: Connectors of the filter heater – a & b) Connection of the power connector, c) Secured power connection, d) Connection of the temperature sensor, e) Secured connection of the temperature sensor.

5.6.7 Connecting the Media Bag Pre-Heater

The media bag pre-heater (Figure 22) is packed in the crate of the accessories and documentation.



Figure 22: Bag Pre-Heater

First hook the upper back part of the media bag pre-heater into the support on the left side of the iCELLis 500+ control system (Figure 23a). After hooking the upper part of the bag pre-heater, install the metric hex screws with a metric hex key of 5 mm, locking the bottom part of the bag pre-heater on the iCELLis 500+ control system (Figure 23b-c).

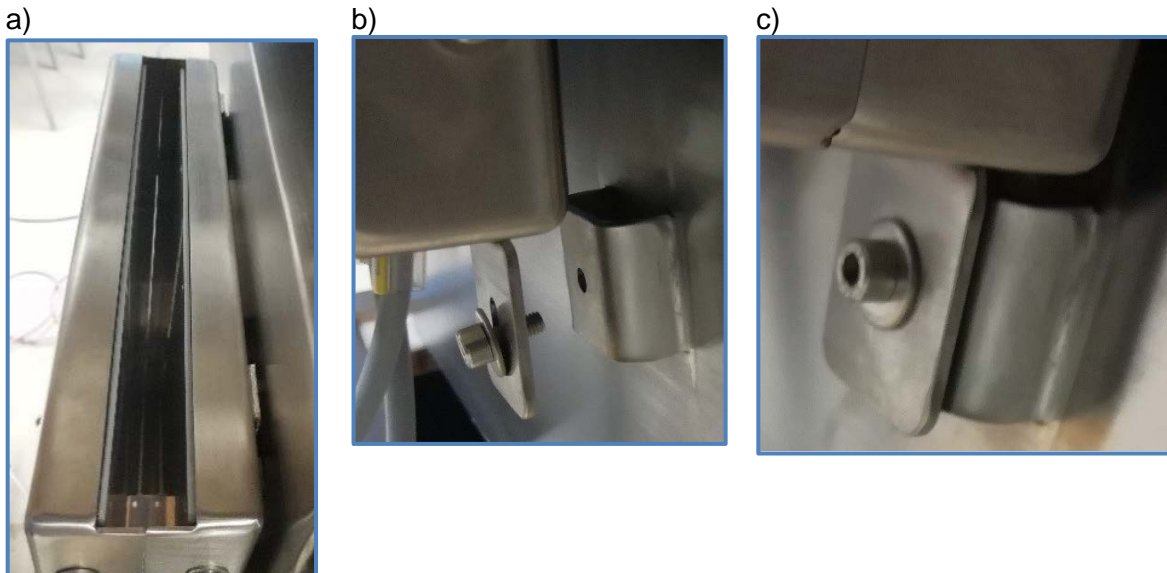


Figure 23. Placing the bag pre-heater – a) Hooking the upper part of the bag pre-heater, b & c) Bolting the bottom part of the bag pre-heater.

Connect the cable with label 'C150/6' to the connector labeled 'C150/6' located to the left of the bag pre-heater (Figure 24a). Secure the connector by turning the metallic part of the connector clockwise.

Connect the cable with label 'C150/8' to the connector labeled 'C150/8' located on the left of the bag pre-heater (Figure 24b). Secure the connector by turning the metallic part of the connector clockwise.

Connect the cable with label 'C26/3' to the connector labeled 'C26/3' located to the left of the bag pre-heater (Figure 24c). Secure the connector by turning the plastic nut/collar a quarter of a turn clockwise.

Connect the cable with the label 'C26/6' to the connector labeled 'C26/6' located to the left of the bag pre-heater (Figure 24d). Secure the connector by turning the plastic nut/collar a quarter of a turn clockwise.

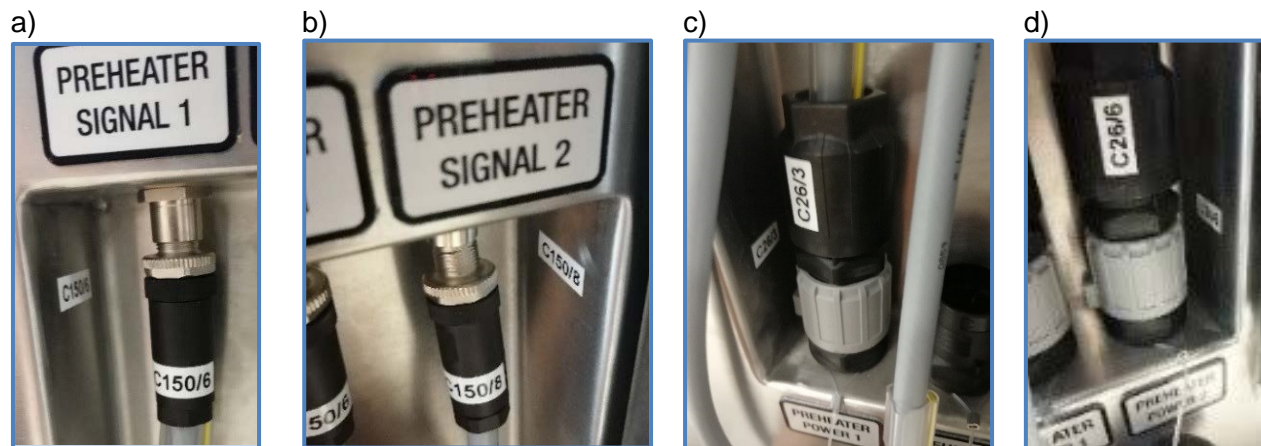








Figure 24: Bag pre-heater connections

5.7 Installation of the Temperature Control Unit (TCU)

-  **DANGER!** Risk of injury to personnel and/or damage to equipment!
Do not install the TCU at a level above the floor level of the iCELLis 500+ control system as this may lead to an over pressure in the double jacket of the bioreactor.
-  **DANGER!** Risk of injury to personnel and/or damage to equipment!
The ingress protection of the TCU is IP 21, please refer TCU user manual for cleaning instructions.
-  **WARNING!** Risk of injury to personnel and/or damage to equipment!
Do not disconnect the communication cable between the iCELLis 500+ control system and the TCU during operation.
-  **WARNING!** Risk of injury to personnel and/or damage to equipment!
Refer to the TCU operating manual provided within the documentation of the iCELLis 500+ control system. Make sure you read and understand all instructions and safety precautions listed in the user manual of the TCU before installing or operating your unit.
-  **WARNING!** Risk of injury to personnel and/or damage to equipment!
Place the TCU on an even surface on a base made of nonflammable material.
-  **WARNING!** HOT/COLD surfaces! Risk of injury to personnel and/or damage to equipment!
Always empty the bath of the TCU before moving the unit. Do not drain the bath fluid while it is hot! Check the temperature of the bath fluid prior to draining (e.g. by switching the unit on for a short moment).



WARNING! Bended tubing! Risk of injury to personnel and/or damage to equipment!

Avoid sharp bends in the fluid tubing of the TCU, and maintain a sufficient distance from surrounding walls. Make sure that the tubing is securely attached.



CAUTION! Risk of injury to personnel and/or damage to equipment!

When the temperature control is active or when the system is cooling down, the TCU media pre-heater and filter heater may become extremely hot. Therefore, exercise particular caution when handling.



ALERT! Risk of damage to equipment!

Never block the cooling fan outlets on the TCU.



There are two different TCU configurations available with the iCELLis 500+ control system. One

configuration must be supplied with 230Vac - 50Hz, and the other must be supplied with 120Vac - 60Hz.

The configuration of the TCU must be specified according to the client requirement during the purchasing of the iCELLis 500+ control system.

The TCU is packed in the crate of the accessories and documentation.

The TCU has been tested to operate with up to 10 meters of tube between the TCU and the bioreactor (10 meters of tube from TCU to DJB In and 10 meters of tube from DBJ Out and TCU). The TCU must be placed in a range less than 10 meters around the iCELLis 500+ bioreactor. The TCU is IP21 rated, please refer to the operating manual of the TCU for cleaning.

Unpack the TCU. Place the TCU on the same floor level as the iCELLis 500+ control system. Connect the TCU to the iCELLis 500+ control system using the PROFIBUS cable between the Interface panel of the TCU (Figure 25a and b) and the dedicated connection slot at the rear of the control system (Figure 25c).

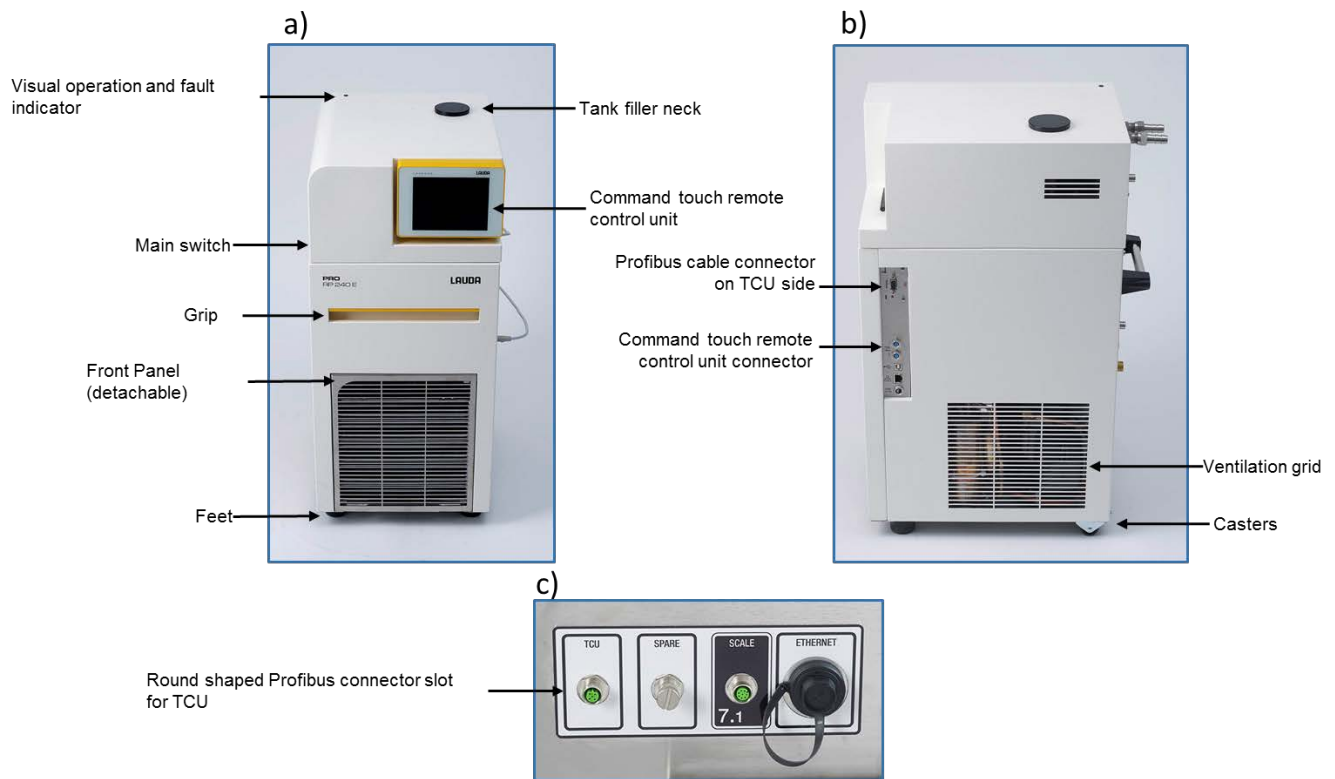


Figure 25: Connection of PROFIBUS cable between TCU and iCELLis 500+ control system –
a) Front of TCU, including Interface panel, b) Side of TCU with Interface panel,
c) Connections at the rear of iCELLis 500+ control system.

Follow Figure 26 to assemble and install the TCU.

Remove the TCU unit from the crate and install it on a flat surface (Figure 26a-b). Place the command touch panel in its designated place on the TCU and connect its cable to the right side of the TCU as shown in (Figure 26c-d).

Take out the Profibus cable from crate and connect one end of the cable to right side of the TCU and other end to back of the iCELLis 500+ control system, tighten the connector on the TCU using a flat screwdriver, please refer to Figure 26e-f.

Confirm the TCU power switch is in the OFF position and connect the power cable to the appropriate voltage supply (230Vac - 50Hz or 120Vac - 60Hz). Refer to the user manual of the TCU for power options. Refer to Figure 26h-i.

Locate the barbed connectors from the crate and remove the nuts from the back side of the TCU IN/OUT lines. Refer to Figure 26j-k. Refer to Figure 26l-o to put nuts on the connectors and connect the combination to the IN/OUT line of TCU.



Figure 26: TCU installation procedure – a) TCU out of the box, b) Command touch panel, c) Connection of touch panel cable, d) TCU with Command touch panel, e) Connection of Profibus connector on TCU, f) Other end of Profibus cable on iCELLis 500+ bioreactor, g) TCU rear side image, h) Power cable, i) Connecting power on rear side of TCU, j) Barbed connectors for IN/OUT line on back of TCU and closure nuts, k) Removing existing closed nuts, l,m,n,o) fixing the connectors with nuts on IN/OUT lines.

5.8 iCELLis 500+ Control System Electrical Installation



WARNING! High voltage!

Always make sure this equipment is properly grounded.



WARNING! Risk of injury to personnel and/or damage to equipment!

Only use the mains power supply cable that is supplied with the unit or that which carries equivalent specification.



ALERT! Risk of damage to equipment!

Never position the iCELLis 500+ control system so that it is difficult to access the machine's mains/power socket. A minimum clearance of 650 mm is required on each side of the iCELLis 500+ control system.



ALERT! Risk of damage to equipment!

Never block the cooling fan outlets on the iCELLis 500+ control system when the iCELLis 500+ control system is powered.

5.8.1 Electrical Power Requirements



Uninterruptible Power Supply (UPS) can be used with the iCELLis 500+ control system according to power supply specifications mentioned in this IFU. The choice of UPS device is at the discretion of the user.

The iCELLis 500+ control system is supplied with its main power supply cable. Only use the cable supplied with the unit. Insure that the iCELLis 500+ control system is connected to suitable overcurrent protection device. Protective grounding for the system is provided through the ground terminal on the plug provided.

Power requirements for iCELLis 500+ control system are displayed in Table 5.

Table 5: iCELLis 500+ control system power requirements

Input voltage (worldwide)	208*/230VAC – 50/60Hz
Maximum power consumption	4,000W

*On a 3 phase 120 Vac network, 208 Vac can be obtained by using the voltage between 2 phases.

5.8.2 Power Connection and Powering ON



PALL recommends turning OFF the iCELLis 500+ control system after each batch, or whenever the system is not in use for a long period of time, to ensure the correct functioning of the equipment.

The main power plug socket and power switch are located on the back of the machine (Figure 27a).

To connect the iCELLis 500+ control system to the power supply, remove the socket protective cap by turning the blue secure lock (Figure 27b-c). Confirm the control system is turned off, connect the power plug firmly (Figure 27d) and secure the connector by turning the blue secure lock. Connect the power cable to the appropriate power supply.

Turn the main power switch to ON to power the control system (Figure 27e-f).

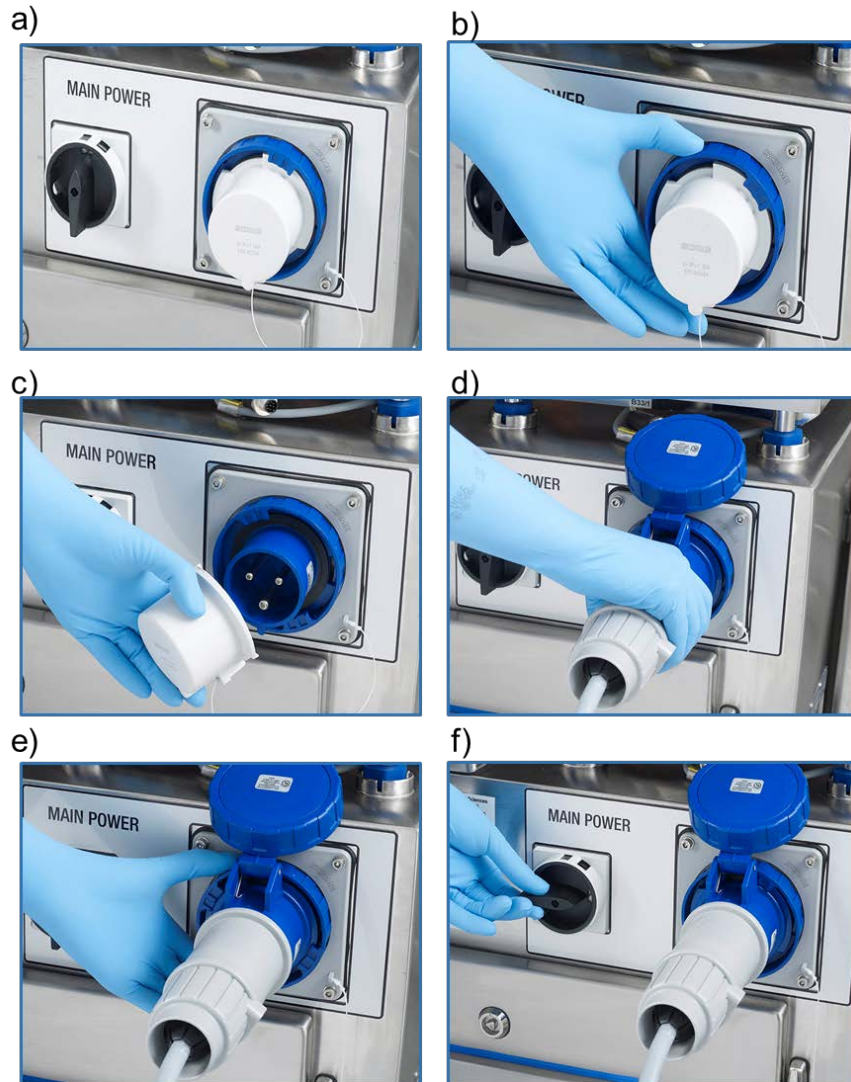


Figure 27: iCELLis 500+ control system powering – a) iCELLis 500+ main power socket and switch, b) Unscrewing protective cap, c) Removing protective cap, d) Plugging power cable, e) Locking power cable, f) Switching ON the control system.

5.9 Fitting the Gas Supplies to the iCELLis 500+ Control System



DANGER! Oxygen causes a fire/explosion risk!

Users are responsible for performing their own safety assessment and obtaining expert advice on the design of any system used to supply gases to the iCELLis 500+ control system.

RELEVANT ONLY WHEN USING OXYGEN: In the unlikely event of a tubing or connection failure, oxygen may build up in and around the iCELLis 500+ control system. A means of independently monitoring oxygen close to the equipment is highly recommended. The monitoring system should be set up to prevent oxygen levels from reaching 24% or limits recommended by local regulations. In the event of a rise in oxygen above this level, the supply should be immediately shut down. The iCELLis 500+ control system can deliver oxygen up to 7 L/min. Oxygen supply to the iCELLis 500+ control system is the user's responsibility.

! DANGER! Risk of asphyxiation!
Carbon dioxide can cause asphyxiation. Ensure that the work space has adequate ventilation. Do not place the system in an enclosed area. The iCELLis 500+ control system can deliver carbon dioxide up to 1.5 L/min. Carbon dioxide supply to the iCELLis 500+ controller is the user's responsibility.

! DANGER! Risk of asphyxiation!
Nitrogen can cause asphyxiation. Ensure that the work space has adequate ventilation. Do not place the system in an enclosed area. Note that the iCELLis 500+ control system can supply nitrogen up to 1.5 L/min. Nitrogen supply to the iCELLis 500+ control system is the user's responsibility.

! WARNING! Risk of injury to personnel and/or damage to equipment!
Gases supplied to the iCELLis 500+ control system must be regulated to specified pressure (maximum 2.5 barg or 36.3 PSIG) and must be oil-free, dry and clean. To prevent possible system component damage, do not exceed these recommendations. Each gas line should be supplied with an ON/OFF valve and an independent pressure regulator.

All materials in contact with the 4 gases are made of stainless steel or USP <88> Class VI material.

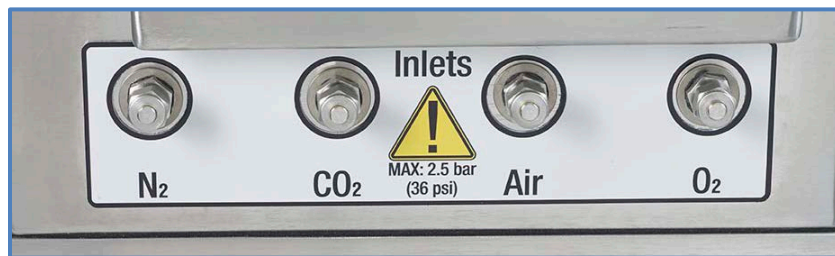


Figure 28: Gas supply inlets of iCELLis 500+ control system

Gas input ports are located on the rear panel of the iCELLis 500+ control system (Figure 28).

Connect external gas supply lines to the iCELLis 500+ control system using the Swagelock ¼ in. OD tube fittings. The 4 gas input connectors on the machine are Swagelock bulkhead unions (SS-400-61) and are delivered with the system (Figure 29). The gas supply lines shall be compatible with the input connectors.



Figure 29: Swagelock bulkhead union for gas lines connections to the iCELLis 500+ control system

Optimal gas delivery pressure to the controller gas inlets are between 2 and 2.5 barg (25 and 36.3 psig). Do not allow gas pressure to exceed 2.5 barg (36.3 psig). A means of independently monitoring of gases close to the equipment is recommended to prevent the risk of a gas leakage.

i Use of 0.2 to 0.45 µm filters between the gas delivery end-point and the iCELLis 500+ control system inlets is highly recommended to prevent mass flow controllers' damage by dust particles. Contact your Pall representative for appropriate references.

6. iCELLis 500+ Control System Specifications

6.1 General Specifications

Compliance with International Standards and Guidelines	
Electromagnetic Compatibility (EMC)	The hardware has met the specification of EN 61326-1: 2013 and FCC CFR 47 Part 15, Sections 15.107 and 15.109 (Class A)
Safety requirements for electrical equipment for measurement, control and laboratory use	The hardware has met the specification of IEC 61010-1:2010 (third edition), IEC 61010-2-010:2014 (third edition), IEC 61010-2-081:2015 (second edition) and IEC 61010-2-051:2015
Restriction of Hazardous Substances (RoHS)	All electrical and electronic components used in the build of the hardware have been certified as compliant to the standard RoHS: Directive 2011/65/EU
CE Marking	The hardware has met the specification of European Directives EMC: 2014/30/EU, Low Voltage Directive (LVD) 2014/35/EU and the Machinery Directive 2006/42/EC
ISO9001: 2008	The product is made in a manufacturing facility where the Quality Management System is ISO9001: 2015 certified
Waste Electrical and Electronic Equipment (WEEE)	The hardware meets the requirements of EC Directive 2012/19/EU
Materials and Specifications	
Control cabinet, probe support, leveling feet, tube retainer, inlet gas filter holder and exhaust filter holder	Main construction material: SS 316L & SS 304
Gas lines – Components in direct contact with gas	Made of stainless steel or USP <88> Class VI material
Dimensions and Weight	
Height	1850 mm (excluding visual alarm and tubing holders) 2122 mm (with visual alarm and tubing holders)
Width	955 mm (excluding optional high flow pump) 1038 mm (with optional high flow pump)
Length	1609 mm
Dry Weight (without bioreactor)	650 kg
Max. Weight when loaded (with bioreactor full of media and double jack full of water)	< 850 kg
Services and Connections to External Circuits	
Electrical power requirements & connections	208*/230VAC – 50/60Hz Power cables included: NEMA L6-30P & 2P+E 32A *On a 3 phases 120 Vac network, 208 Vac can be obtained by using the voltage between 2 phases

Gas connections	Air, carbon dioxide, oxygen and nitrogen are connected to the iCELLis 500+ control system using Swagelock ¼ in. tube OD (female connector on the iCELLis 500+ control system). All gases must be supplied dry and oil free and they must be regulated to a maximum of 2.5 barg (36.3 psig).																										
Connections provided for additional input/output	1 spare connector available at the back of the machine for additional input/output based on customization request.																										
Sensors																											
Single-use pH sensors	2 optical based disposable pH sensors for measurement of disposable bioreactor internal pH, 1 sensor at the center before the fixed-bed, 1 sensor after the fixed-bed.																										
Single-use DO sensors	2 optical based disposable DO sensors, 1 sensor at the center before the fixed-bed, 1 sensor after the fixed-bed.																										
Single-use pressure sensors	1 disposable pressure sensor for measurement of disposable bioreactor internal pressure. 1 disposable pressure sensor for measurement of double jacket line pressure.																										
Temperature sensors	2 pt100 sensors for measurement of disposable bioreactor internal temperature.																										
Functions																											
Agitation	Agitation is provided by a bottom-mounted impeller in the iCELLis disposable bioreactor. The impeller is magnetically driven. The impeller speed can be set via the iCELLis 500+ software between 0 and 450 rpm.																										
Temperature control	Bioreactor internal temperature control using double jacket integrated in the disposable bioreactor and external TCU.																										
Aeration	Gas overlay: Air, carbon dioxide, oxygen and nitrogen, can be delivered at a maximum combined gas flow rate of 7 NL/min.																										
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Gas MFC</th> <th style="text-align: center;">Max. Flow Capacity (L/min)</th> <th style="text-align: center;">Automatic Mode (L/min)</th> <th style="text-align: center;">Manual Mode (L/min)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">CO₂</td> <td style="text-align: center;">1.5</td> <td style="text-align: center;">1.5</td> <td style="text-align: center;">1.5</td> </tr> <tr> <td style="text-align: center;">N₂</td> <td style="text-align: center;">1.5</td> <td style="text-align: center;">1.5</td> <td style="text-align: center;">1.5</td> </tr> <tr> <td style="text-align: center;">Air</td> <td style="text-align: center;">3</td> <td style="text-align: center;">3</td> <td style="text-align: center;">3</td> </tr> <tr> <td style="text-align: center;">O₂</td> <td style="text-align: center;">7</td> <td style="text-align: center;">7</td> <td style="text-align: center;">7</td> </tr> <tr> <td style="text-align: center;">Total Gas Flow</td> <td style="text-align: center;">13</td> <td style="text-align: center;">0 to 7</td> <td style="text-align: center;">13*</td> </tr> </tbody> </table>			Gas MFC	Max. Flow Capacity (L/min)	Automatic Mode (L/min)	Manual Mode (L/min)	CO ₂	1.5	1.5	1.5	N ₂	1.5	1.5	1.5	Air	3	3	3	O ₂	7	7	7	Total Gas Flow	13	0 to 7	13*
Gas MFC	Max. Flow Capacity (L/min)	Automatic Mode (L/min)	Manual Mode (L/min)																								
CO ₂	1.5	1.5	1.5																								
N ₂	1.5	1.5	1.5																								
Air	3	3	3																								
O ₂	7	7	7																								
Total Gas Flow	13	0 to 7	13*																								
	*It is only possible to achieve the maximum total gas flow capacity in the manual mode of each line, setting each line to its maximum value. The total gas flow will be the sum of all the maximum individuals gas flows (13L/min)																										
Pumps	Variable speed peristaltic pumps from 0 to 360 rpm (minimum recommended speed is 25 rpm). Maximum theoretical flow of the Watson Marlow* 520 pump head with high flow manifold (PharMed BPT ID: 3/8 in.): 5,4L/min Maximum theoretical flow of the Watson Marlow 520 pump head with low flow manifold (PharMed BPT ID: 1/2 in.): 2,4L/min																										
Weight measurement	Load cells provide ability to measure weight of the iCELLis 500+ bioreactor																										
Bioreactor over-pressure protection	Interlock using disposable pressure sensor for measurement of bioreactor internal pressure																										

Double jacket over-pressure protection	Interlock using disposable pressure sensor for measurement of the double jacket internal pressure
Emergency stop	2 emergency stop buttons, 1 on the front and 1 on the left side of the iCELLis 500+ control system Top Assembly.
Power failure data protection	Integrated UPS for the safe shut down of the computer only. A power supply UPS is highly recommended
Software platform	Wonderware* ArchestrA system platform
Data storage capacity	2 x SSD of 240 Go (RAID1 for redundant data storage)
Electronic records & electronic signatures	Compatible with FDA 21 CFR Part 11 and Eudralex Annex 11
Automation design	Developed and tested in accordance with GAMP5 guidelines
Data export/Network communication	Integrated OPC server for real-time data monitoring. Access to SQL database for historical data storage
HMI	19 in. touch panel & USB interface
Remote operation	Available via Windows* Remote Desktop Protocol
Cleaning solutions	Recommended cleaning solutions for wiping exposed surfaces of the hardware: <ul style="list-style-type: none"> • Water • 70% (v/v) ethanol in water • Isopropyl alcohol (IPA)
Recommended preventative maintenance interval	12 months
Storage temperature	4 °C – 40 °C
Maximum relative humidity in storage	80% RH, non-condensing
Operating temperature	18 °C – 25 °C
Relative humidity during operation	10 – 70% RH, non-condensing
Noise pressure level	< 85dBA

6.2 Sensors and Actuators Specifications

TAG P&ID	Description	Range	Accuracy	Unit
TT_01	Temperature culture media before fixed-bed T1	0,0 ... 50,0	+/- 0.3	°C
TT_02	Temperature culture media before fixed-bed T2	0,0 ... 50,0	+/- 0.3	°C
TT_03	Temperature pre heater bag 1	0,0 ... 100,0	+/- 1.0	°C
TT_04	Temperature pre heater bag 2	0,0 ... 100,0	+/- 1.0	°C
TT_05	Temperature heating system TCU	0,0 ... 50,0	+/- 1.0	°C
TT_06	Temperature of exhaust heater	0,0 ... 100,0	+/- 2.0	°C
AT_01	pH culture media before fixed-bed Polestar pH1	6.5 ... 8.5	+/- 0.1 ¹	N/A
AT_02	pH culture media after fixed-bed Polestar pH2	6.5 ... 8.5	+/- 0.1 ¹	N/A
AT_03	DO culture media before fixed-bed Polestar DO1	0 ... 150	+/- 3.5 between 15 and 75%, else +/- 7%	%airsat
AT_04	DO culture media after fixed-bed Polestar DO2	0 ... 150	+/- 3.5 between 15 and 75%, else +/- 7%	%airsat
AT_05	Biomass of the fixed-bed in mS/cm	-2,0 ... 40,0	+/- 3.0%	mS/cm
AT_06	Biomass of the fixed-bed in pF/cm	-5 ... 400	+/- 3.0%	pF/cm
FT_01	CO ₂ flow transmitter	0,00 ... 1,50	+/- 0.1	NL/min
FT_02	N ₂ flow transmitter	0,00 ... 1,50	+/- 0.1	NL/min
FT_03	Air flow transmitter	0,00 ... 3,00	+/- 0.1	NL/min
FT_04	O ₂ flow transmitter	0,00 ... 7,00	+/- 0.1	NL/min
PT_01	Pressure double jacket	0,0 ... 300,0	+/- 5.0	mbarg
PT_02	Pressure bioreactor	0,0 ... 100,0	+/- 5.0	mbarg
PT_03	Pressure middle assembly	0 ... 250	+/- 10.0	mbarg
WT_01	Weight base bag	0,00 ... 60,0	+/- 0.1	Kg

¹ The correct level of accuracy can only be expected at the pH value at which the 1-point calibration is performed. The greater the distance from the point of calibration, the lower the probability that the accuracy will be within specification. Therefore, if these bioreactors demonstrate a greater distance, then Pall's recommendation is that the bioreactors can only be used under mitigation actions, specifically manual pH control. Our dedicated Application team can give you support for these mitigation actions.

WT_02	Weight bioreactor	0 ... 180,0	+/- 1.0% of liquid weight (agitation from 0 - 300 rpm) +/- 3.0% of liquid weight (agitation from 300-450 rpm)	Kg
ST_01	Speed feed-in pump (Watson Marlow 520R pump head)	0 ... 360	+/- 2.0	rpm
ST_02	Speed base pump (Watson Marlow 313DW pump head)	0 ... 360	+/- 2.0	rpm
ST_03	Speed inoculum pump (Watson Marlow 313DW pump head)	0 ... 360	+/- 2.0	rpm
ST_04	Speed feed-out pump (Watson Marlow 520R pump head)	0 ... 360	+/- 2.0	rpm
ST_05	Speed sampling pump (Watson Marlow 313DW pump head)	0 ... 360	+/- 2.0	rpm
ST_06	Speed agitation system	0 ... 450	+/- 5.0	rpm
ST_07	Speed fill pump (optional) (Watson Marlow 630BpN)	0 ... 160	+/- 2.0	rpm
ST_08	Speed drain pump (optional) (Watson Marlow 630BpN)	0 ... 160	+/- 2.0	rpm

6.3 Temperature Control Unit Specifications

Description	LAUDA PRO RP 240 EC 230V 50Hz	LAUDA PRO RP 240 EC 120V 60Hz
Working temperature range (°C)	-40 ... +200	-40 ... +200
Temperature stability (°C)	±0.05	±0.05
Setting / display resolution	0.01 °C	0.01 °C
Temperature display	TFT touchscreen	TFT touchscreen
Electric current consumption (A)	16	16
Heating capacity (kW)	2.5	1.8
Pump capacity flow rate (L/min)	22	22
Pump capacity flow pressure (bar)	0.7	0.7
Pump capacity flow suction (bar)	0.4	0.4
Process volume min (L)	2.4...4.4	2.4...4.4
Digital interfaces	Profibus	Profibus
Ambient temperature (°C)	5...40	5...40

7. Cleaning



WARNING! Risk of injury to personnel and/or damage to equipment!

Never spray liquid or allow any ingress of fluid of any sort into the hardware cooling fan ports on the back and bottom of the iCELLis 500+ control system.



WARNING! Risk of damage to equipment!

Always switch off power to iCELLis 500+ control system, and then disconnect the mains/power cable before cleaning the hardware.



WARNING! Risk of injury to personnel and/or damage to equipment!

Cleaning solutions containing alcohols are flammable. Care should be taken when using these solutions.



ALERT! Risk of damage to equipment!

The use of solutions containing low molecular weight alcohol, especially isopropyl alcohol, to decontaminate the exterior of the iCELLis 500+ bioreactor may, in circumstances where significant stress (repetitive bending and twisting) is applied during use, cause damage to the molded LDPE inlet and outlet ports.

It is recommended that before and after every use, all exposed surfaces of the iCELLis 500+ control system are cleaned.

Before any cleaning operation, close the doors and lock all lockers to ensure the proper compression of the gasket. Ensure that all the caps are placed on all the connectors.

Ensure that the tube holder accessories are removed and the fixing bolts placed on the top of the machine with the proper gasket washers.

A soft, damp cloth moistened with the following recommended cleaning solutions should be used:

- Water
- 70% (v/v) ethanol in water
- Isopropyl alcohol (IPA)

8. Maintenance

If any problems occur with the hardware, no attempt should be made to perform any maintenance on it as it may void any warranties. Please contact Pall (See Section 10).

In any correspondence with Pall, the model, manufacturing part and serial numbers of the hardware should be recorded for reference.

It is recommended to change the filters of the cooling inlet and outlet periodically.
An annual periodical maintenance performed by Pall service team is recommended.

9. Disposal

To dispose of the iCELLis 500+ control system, the relevant legal regulations must be observed. Within the European Community, the disposal of electrical devices is regulated by national regulations based on EU directive 2002/96/EC pertaining to waste electrical and electronic equipment (WEEE). According to these regulations, any device supplied after August 13, 2005, in the business-to-business sphere (to which this product is assigned), may no longer be disposed of in municipal or domestic waste. To document this, they have been marked with the following symbol:



Please visit our website for more information and local instructions on disposing of the product at <https://www.pall.com/en/about-pall/corporate-sustainability/weee-compliance.html>.

10. Technical Assistance

For technical assistance, please contact:

- Your local Pall representative
- Visit www.pall.com
- E-mail your enquiry to bioreactors@pall.com

Or contact Pall:

Corporate Headquarters 25 Harbor Park Drive Port Washington, NY 11050, USA +1.800.717.7255 toll free (USA) +1.516.484.5400 phone biopharm@pall.com e-mail	European Headquarters Avenue de Tivoli 3, 1700 Fribourg, Switzerland +41 (0)26 350 53 00 phone LifeSciences.EU@pall.com e-mail	Asia-Pacific Headquarters 1 Science Park Road, #05-09/15 East Wing, The Capricorn, Singapore Science Park II, Singapore, 117528. +65 6389 6500 phone sgcustomerservice@pall.com e-mail
---	---	---

Appendix A: Abbreviations and Symbols

Abbreviation, Symbol	Signification
A	Ampere
Barg, mbarg	Bar, millibar, gauge pressure
CE	Declaration of European conformity
DO	Dissolved Oxygen
GMP	Good Manufacturing Practice
HMI	Human Machine Interface
Hz	Hertz
IPA	Isopropyl Alcohol
m, mm	Meter, millimeter
MFC	Mass Flow Controller
OD	Outer Diameter
P&ID	Piping and Instrumentation Diagram
PET	Polyethylene terephthalate
PETG	Polyethylene Terephthalate Glycol
PLC	Programmable Logic Controller
PSIG	Pounds per Square Inch gauge pressure
rpm	Revolution per minute
TCU	Temperature Control Unit
TFT	Thin Film Transistor
Vac,	Volt alternating current
W	Watt



Biotech

Corporate Headquarters

Port Washington, NY, USA
+1 800 717 7255 toll free (USA)
+1 516 484 5400 phone
biopharm@pall.com e-mail

European Headquarters

Fribourg, Switzerland
+41 (0)26 350 53 00 phone
LifeSciences.EU@pall.com e-mail

Asia-Pacific Headquarters

Singapore
+65 6389 6500 phone
sgcustomerservice@pall.com e-mail

Filtration. Separation. Solution.sm


Visit us on the Web at www.pall.com/bioreactors

E-mail us at bioreactors@pall.com

Pall Corporation has offices and plants throughout the world in locations such as: Argentina, Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, India, Indonesia, Ireland, Italy, Japan, Korea, Malaysia, Mexico, the Netherlands, New Zealand, Norway, Poland, Puerto Rico, Russia, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, the United Kingdom, the United States, and Venezuela. Distributors in all major industrial areas of the world. To locate the Pall office or distributor nearest you, visit www.pall.com/contact.

The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

Pall, the Pall logo, Allegro and Kleenpak are trademarks of Pall Corporation. Because of technological developments related to the products, systems, and/or services described herein, the data and procedures are subject to change without notice. Images or figures are used for illustrative purposes only and may vary slightly to the product you are installing. Please consult your Pall representative or visit www.pall.com to verify that the information remains valid.

© 2018, Pall Corporation. Pall, , iCELLis is a trademarks of Pall Corporation. ® indicates a trademark registered in the USA and TM indicates a common law trademark.

Filtration.Separation.Solution.SM is a service mark of Pall Corporation. * Watson Marlow is a trademark of Watson Marlow Ltd, Windows is a trademark of Microsoft Corporation, Wonderware is a trademark of Schneider Electric.

Patents: Pall.com/patents

USD3310