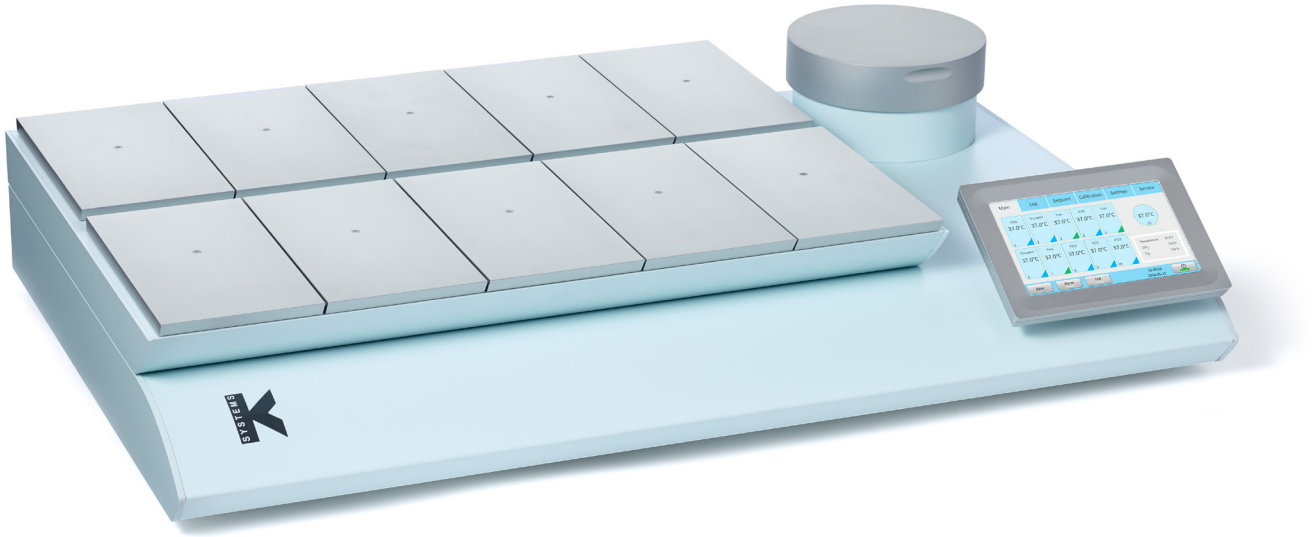
G210 InviCell™

Long Term Incubator

User Manual



Models: G210 InviCell Standard

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CE 2797

℞ Only

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SECTION 1 - PREFACE

Thank you for choosing a K-Systems product.

At CooperSurgical, we strive to provide the very best products and solutions for human IVF and the G210 InviCell™ is designed to provide optimum conditions for gametes and embryos during long term culture.

For optimal use of the G210 InviCell, please read and follow the instructions in this User Manual.

The incubator should be operated by trained personnel only. All sections of this manual should be read and understood fully before any operation of the incubator. If the operator is unsure of any of the information contained in this manual they should contact Customer Services or an appointed representative before attempting to use this equipment. Keep these instructions close to the device. This ensures easy access to the safety instructions and important information.

In no event does CooperSurgical assume the liability for any technical or editorial errors of commission, or omission; nor is liable for direct, indirect, incidental, or consequential damages arising out of the use or inability to use this manual.

The information in this manual is current at the time of publication. Our commitment to product improvement requires that we reserve the right to change equipment, procedures and specifications at any time. This user manual belongs with the G210 InviCell incubator and should be passed on with the incubator if relocated to another facility.

EC REP

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SECTION 2 - INTRODUCTION

The G210 InviCell™ is a bench-top long term incubator comprised of ten independent chambers for gamete/embryo development and one larger preparation chamber. The larger preparation chamber is not used for embryo development. The device is a non-sterile, reusable piece of equipment.

The incubator is used to culture gametes and embryos for up to 6-7 days in a controlled environment (temperature, CO_2/O_2), normally in culture media contained within a culture dish. The CO_2 and O_2 concentration are monitored by sensors located in a chamber internal to the incubator chassis. The gas is constantly recirculated from the culture chambers through a HEPA (high-efficiency particulate air)/VOC (volatile organic compound) filter.

Indications for Use

The K-System G210 InviCell Standard Incubator is a bench-top incubator that is intended to provide a controlled environment at or near body temperature and gas levels for the development of gametes and/or embryos during In Vitro Fertilization (IVF)/Assisted Reproductive Technology (ART) treatments.

Intended Purpose

G210 InviCell long term Incubators are applied in ART treatments and are intended to provide an environment with controlled temperature at or near body temperature, pH and O_2 level for the development of gametes and embryos during in vitro fertilization (IVF)/assisted reproductive technology (ART) treatments.

Principal Mode of Operation

The primary function is to allow the storing and culture of human gametes and embryos providing environmental conditions similar to the human fallopian tube and uterus in terms of controlled temperature and physiological pH and oxygen levels via gas mixture levels (CO_2 and O_2) during in vitro Fertilization (IVF)/assisted reproductive technology (ART) procedures.

Disease/ conditions to be treated

G210 InviCell long term Incubators are used in the treatment of infertility (male and/or female), a disease defined by the World Health Organization (WHO) as a failure to achieve pregnancy after 12 months of regular unprotected sexual intercourse (Zegers-Hochschild et al. 2017).

One in six couples experience some form of infertility during their reproductive lifetime, due to female factors, male factors, problems in both partners, as well as cases where no cause is found (unexplained/ idiopathic infertility). Increasing age in the female partner is one of the most common explanations for infertility, but also age of the male partner, as well as lifestyle factors such as smoking, bodyweight, and stress all influence ART success rates (Eisenberg and Meldrum 2017; ESHRE 2018). In women, infertility is commonly caused by ovulatory dysfunction, tubal obstructions and/or endometriosis. Whereas in men, infertility is a result of abnormalities in sperm production and function, or sperm duct blockages (Nardelli et al. 2014). When lifestyle changes alone are not sufficient, treatment mainly falls into three categories (NCC-WCH 2013):

- Medical treatment to restore fertility (e.g. drugs for ovulation induction)
- Surgical treatment to restore fertility (e.g. laparoscopy for ablation of endometriosis)
- ART treatment, including all kinds of conception other than normal coitus, involving a large variety of techniques for in vitro handling of gametes and embryos (incl. intrauterine insemination (IUI)/artificial insemination, in vitro Fertilization (IVF), and intracytoplasmic sperm injection (ICSI).

Intended user and environment of use

The product should only be used by professionals trained in ART procedures, such as embryologists, gynecologists, and laboratory technicians in a controlled clinical environment.

Patient Target Group

G210 InviCell long term Incubators can be used for all persons/couples assessed suitable for ART treatment by a gynecologist.

Type of contact

G210 InviCell long term Incubators do not come into direct contact with human reproductive tissues.

Contraindications

There are no contraindications associated with this device.

Applicable Part Numbers

K59500 G210 InviCell Standard Incubator

G210 InviCell requires installation by CooperSurgical service personnel.

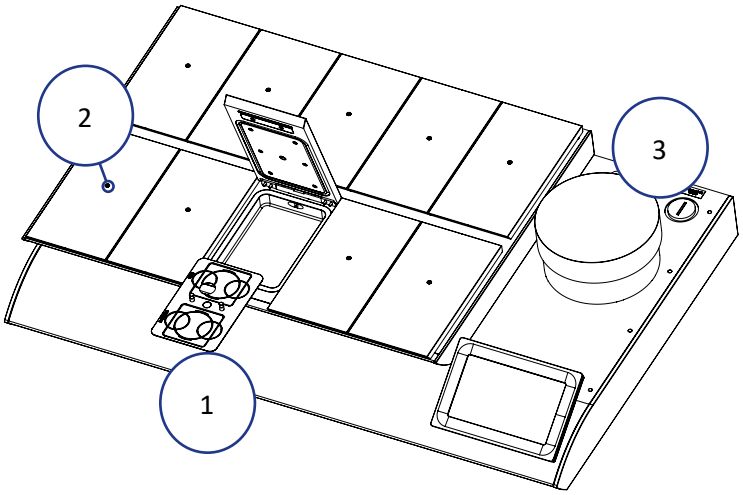
Significant Performance Characteristics

The incubator has been developed and optimized for gametes and embryos cultured with an overlay of either paraffin or mineral oil. Each chamber is designed to contain dishes from one patient only.

Operation Principle

The fertilized egg (zygote) is cultured for up to 6-7 days in a growth medium in the incubator with a controlled environment (temperature and CO_2/O_2). It is then implanted in the same or another woman's uterus, with the intention of establishing a successful pregnancy.

Ensure the culture dishes are placed securely in the correct milled grooves of the Dish Inserts.



Dish Inserts

The chambers should only be fitted with special Dish Inserts (1), that allow safe placement of standard culture dishes (LifeGlobal, Falcon, Nunc, Vitrolife).

Culture Chamber

Each chamber is equipped with individual temperature sensors and heating control, to ensure a uniform heat distribution.

Unidirectional gas flow within each chamber ensures even gas distribution.

Chamber Lid

Each lid has a sensor that, when opened, will disconnect the gas flow to minimize ambient air entering the gas system. The gas flow restarts immediately after closing the lid.

The silicone plugs (2) in the lid of each chamber are for the collection of gas samples. These plugs should be replaced when penetrated a maximum of 5 times.

Preparation Chamber

The Preparation Chamber (3) is intended to be used for the equilibration and heating of pre-filled culture dishes with an oil overlay or flask of oil.

The Preparation Chamber also has a lid sensor which will disconnect the gas flow when the lid is opened, to minimize the ingress of ambient air into the gas system. The gas flow restarts immediately after closing the lid.

Gas flow to the Preparation Chamber can be disconnected through the user interface (see page 28).

SECTION 3 – SAFETY WARNINGS

Safety and Reliability

Please read this manual carefully and follow the instructions to ensure that the system will work safely and reliably. Safety is the responsibility of the laboratory. Risk assessment and working practices should comply with local regulatory policies.

Warnings

WARNING: Use only 100% pure CO_2 and 100% pure N_2 gas. Use of other gases could result in serious injury, depending on the gas connected.

WARNING: DO NOT disassemble or modify any part of the G210 InviCell, or substitute any component for any other. Doing so may result in damage to samples. This voids the warranty and/or service contract.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a mains supply with protective earth.

WARNING: Not to be used in a patient environment.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Cautions

CAUTION: Ensure the device is protected against power disruption by using a system, such as a Uninterruptible Power Supply, to provide emergency power if the mains power fails.

CAUTION: Read and understand the manual completely before use. Keep the manual close to the unit.

CAUTION: Do not move the device once it has been installed. If the incubator needs to be relocated, please contact Customer Service.

CAUTION: Never use the unit if the alarm system of the device has issued a failure message and the cause of the failure has not been identified.

CAUTION: Protect the power cord from being damaged or being restricted in any way. Unplug the power cord from the wall socket or at the rear of the instrument to disconnect the mains supply.

CAUTION: Make sure that CO_2 and N_2 gas supply pressures are maximum 1.0 bar and not below 0.5 bar.

CAUTION: Always keep the red cap on unused gas inlets at the back of the unit and the protection cap on the sample port placed behind the Preparation Chamber.

CAUTION: Never use the unit without a genuine ORIGIO Gas Line Filter.

CAUTION: DO NOT expose the filter to liquids. Change filters that have been exposed to liquids.

CAUTION: DO NOT leave lids open for more than 20 seconds.

CAUTION: DO NOT use the unit at ambient temperatures exceeding 30°C. Ambient temperature above 30°C will compromise the incubation process.

CAUTION: DO NOT raise the top section of the incubator with samples in the incubation chambers.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The G210 InviCell is intended for use in the electromagnetic environment specified below. The customer or the user of the G210 InviCell should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR11	Group 1	The G210 InviCell uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class A – Complies	The G210 InviCell is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A - Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class A - Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The G210 InviCell is intended for use in the electromagnetic environment specified below. The customer or the user of the G210 InviCell should assure that it is used in such an environment.			
IMMUNITY Test	**IEC 61326-1 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 4 kV contact ± 2, 4, 8 kV air	± 2, 4 kV contact ± 2, 4, 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	+/- 1.0kV Burst Potential - Mains +/- 0.5kV Burst Potential - Signals/Control	+/- 1.0kV Burst Potential - Mains +/- 0.5kV Burst Potential - Signals/ Control	
Surge IEC 61000-4-5	Line-Line: 0.5kV Combination Wave (1.2µS x 50µS Voltage, 8µS x 20µS Current) Line-Earth: 0.5kV & 1.0 kV Combination Wave (1.2µS x 50µS Voltage, 8µS x 20µS Current)	Line-Line: 0.5kV Combination Wave (1.2µS x 50µS Voltage, 8µS x 20µS Current) Line-Earth: 0.5kV & 1.0 kV Combination Wave (1.2µS x 50µS Voltage, 8µS x 20µS Current)	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100% Reduction; 0.5-1 50Hz Period Cycles; 0° & 180° Sync Angle 30% Reduction; 0.5s Duration; 25 50Hz Period Cycles; 0° & 180° Sync Angle 100% Reduction; 5s Duration; 250 50Hz Period Cycles; 0° Sync Angle	100% Reduction; 0.5-1 50Hz Period Cycles; 0° & 180° Sync Angle 30% Reduction; 0.5s Duration; 25 50Hz Period Cycles; 0° & 180° Sync Angle 100% Reduction; 5s Duration; 250 50Hz Period Cycles; 0° Sync Angle	

IMMUNITY Test	IEC 61326-1 Test level	Compliance level	Electromagnetic environment - guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms, 0.150-80Hz, 80% AM Modulation, 1s Dwell Time 3 V/m 80 MHz to 1000 MHz 3V/m 1400 MHz to 6000 MHz 1V/m 2000 MHz to 2700 MHz	3Vrms, 0.150-80Hz, 80% AM Modulation, 1s Dwell Time 3 V/m 3V/m 1V/m	Portable and mobile RF communications equipment should be used no closer to any part of the G210 InviCell, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance $d = [\frac{3,5}{3}]\sqrt{P}$ $d = [\frac{3,5}{3}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{3}]\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the G210 InviCell is used exceeds the applicable RF compliance level above, the G210 InviCell should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the G210 InviCell.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Glossary of Safety and Information Symbols

Source: ISO 15223-1, BS EN 61010-1 and ISO 7000

Symbol	Meaning	Symbol	Meaning
CE 2797	In accordance with Annex II of the European Medical Device Directive 93/42/EEC, as amended by Directive 2007/47/EC	REF	Catalogue or Part number
Rx Only	Caution: US Federal law restricts this device for sale to or on the order of a licensed healthcare practitioner	SN	Serial Number
EC REP	Authorized representative in the European Community	MD	Medical Device
	Consult instructions for use or consult electronic instructions for use	UDI	Unique Device Identifier
c UL us LISTED LABORATORY EQUIPMENT E472681	This electrical product is independently certified by UL	CC	Country of manufacture ("CC" shall be replaced by either the two letter or three letter country code)
	WARNING: Indicates a potentially hazardous situation which, if not avoided, could result in serious injury or death		Keep dry
	CAUTION: Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury		Fuse
	Biological risks		Do not dispose of product with normal waste. Dispose of in accordance with the EU WEEE Directive. (See Care and Maintenance section.)
	Manufacturer		Ethernet Port

	Date of Manufacture		This way up
WARRANTY Void IF BROKEN	Warranty label		Importer
Sample Port	Gas Inlets CO_2/N_2		Fragile, handle with care
GAS (MAX 1 BAR)	Sample Port		

SECTION 4 - INSTALLATION

Installation of the G210 InviCell should be carried out by a CooperSurgical Service Technician or other authorized personnel. Incorrect installation could result in overall poor performance.

The G210 InviCell is designed as a stationary unit and, therefore, not to be moved once it has been installed. If the incubator needs to be relocated, please contact Customer Service.

Placement

Environment	
Temperature	20 - 30°C
Humidity	Less than 75% (non-condensing)
Placement	On a flat, hard and stable surface. Unit must be kept away from heating and cooling devices.
Clearance	Allow at least 2cm clearance from the rear, 30cm from the top and 20cm from left and right for proper ventilation.
Environment	**Indoor use only.** Avoid high temperature, moisture, water and dust. This unit must not be exposed to dripping or splashing. This unit is designed for use at altitudes under 2000m.

CAUTION: Installation of the unit should only be performed by an authorized CooperSurgical Service Technician.

SECTION 5 - PRODUCT OVERVIEW

Main Components

Components	
1	Incubator Chambers
2	Touchscreen
3	Preparation Chamber
4	ORIGIO Gas Line Filter
5	Port for external CO_2 sensor (shown with adaptor fitted)
6	Product label
7	Mains inlet with fuse
8	Temperature signal connection for external monitoring
9	Power connection for external monitoring
10	Gas inlet connectors
11	Alarm output
12	Ethernet connector*

*External computing devices connected to the Ethernet on the unit must only be Limited Power Source and SELV circuit according to the standard IEC 62368-1

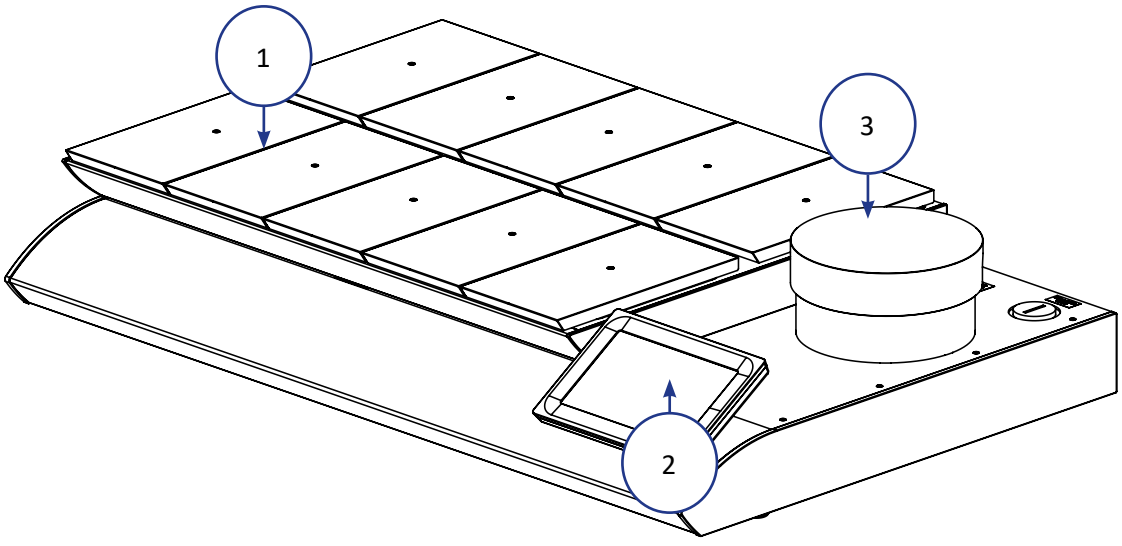


Figure 5-1 G210 InviCell Standard - front view

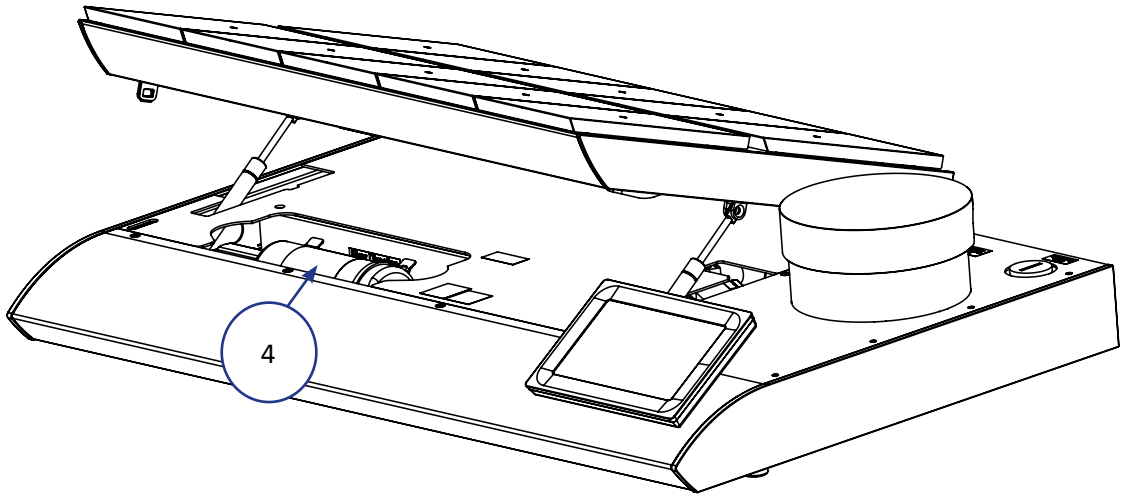


Figure 5-2 G210 InviCell Standard - raised top section

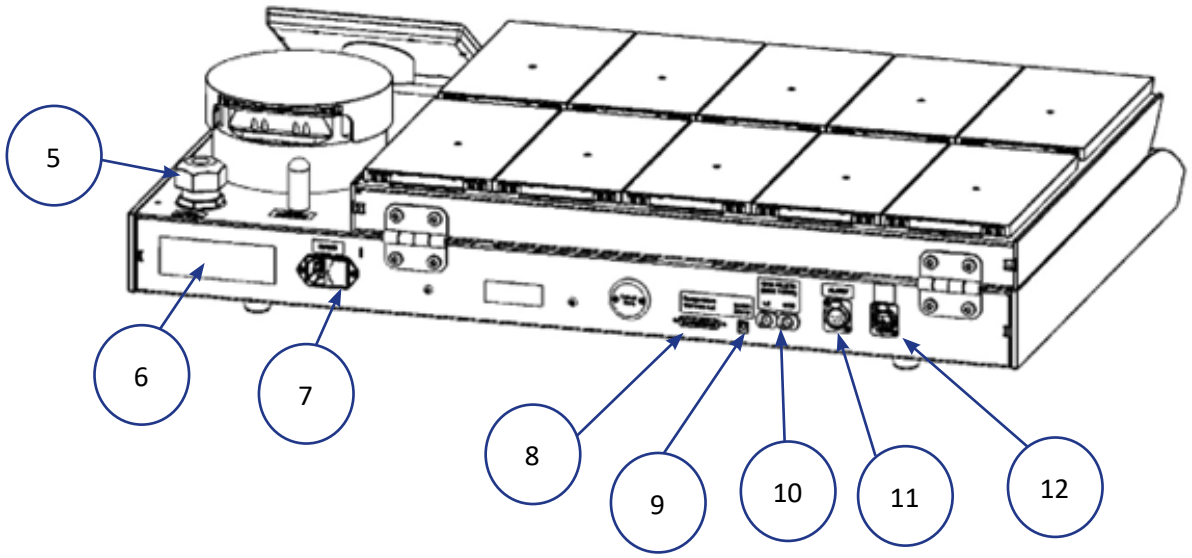


Figure 5-3 G210 InviCell Standard Model - back view

IT Security

The G210 InviCell does not require a connection to a network or to a computer to perform its normal function. It may be connected to a Windows computer through an RJ45 connection that will allow communication with K-Link software. In this case, we recommend PC security features such as anti-virus software and firewall be installed on the PC consistent with the facility's IT policy, and that each user of the PC has a password-protected user profile in order to prevent unauthorized access.

Firmware updates must only be done by CooperSurgical authorized service personnel.

Supplied Parts for G210 InviCell Standard

- 1 x ORIGIO Gas Line Filter
- 2 x HEPA Inline Filter for input gas supply
- 10 Dish Inserts for LifeGlobal, Nunc®, Falcon® or Vitrolife® Customers to specify number and type when ordering (minimum ordering quantity of 10)
- 2 x Silicone Tube Sealing Rings & Silicone Tube (3m)
- Gas sampling coupling
- 4 power cords: UK, EU, US, AU/CN
- 1 LAN cable (3m)
- 1x packet of 10 Chamber Lid Plugs
- 1x USB drive containing K-Link software
- 2x adaptors for external cylindrical CO_2 sensors between 11 and 25mm diameter

Optional Order Codes

Order Code	Description
K23063-1	Falcon Dish Inserts 1 pc
K23064-1	Nunc Dish Inserts 1 pc
K23069	Vitrolife Dish Inserts 1 pc
K23070	LifeGlobal Dish Inserts 1 pc
ULTRA-001	Gas Line Filter
K53830	HEPA Inline Filter
K59922	Lid Plugs, bag of 10
K59901-1	Lid Seal for culture chambers
K59902-1	Lid Seal for Preparation Chamber
K59688	Gas sampler coupling
K11103	G100 Gas Analyzer
K11006	Solid Temperature Sensor (use with K-Systems F100 Thermometer)
K59655	XLR6 Receptacle Connector
K32903	G210 InviCell User Manual
K60017	Connector for External CO_2 sensor 18-25mm
K60014	Connector for External CO_2 sensor 11-21mm
K60019	24VDC power supply for external monitoring

Specification Table

Criteria	Specification
Overall dimensions, (L x W x H)	855mm x 570mm x 180mm
Weight	45kg
Temperature range	35 – 42°C
User interface	Touchscreen
User interface functions	Digital temperature readout, data logger, temperature setpoint, calibration, warning for next service
Connections	Mains power, CO_2 gas, N_2 gas, Sample port, Ethernet, Alarm
Alarms	Visual and audible alarm for out of range temperature and gas
Filter (HEPA/ VOC)	ORIGIO Gas Line Filter
Power specifications 100 – 240 VAC	
Max consumption	270W
Voltage	L/N/PE AC, 100 - 240VAC Class 1 type B
Frequency	50/60Hz
Current	3A
Mains supply voltage fluctuations	Up to +/-10% of the nominal voltage
Fuses 100 - 250V UL Listed	
Mains connection	T4.0AL
Ambient Conditions	
Working temperature and humidity	20 – 30°C. Less than 75% RH (non-condensing)

SECTION 6 - MONITORING

G210 InviCell supports external and independent monitoring of parameters regarding the performance of culture media: CO_2 concentration and temperature.

All external monitoring is independent of the functions and controls in the G210 InviCell as they are connected to and powered by independent instruments.

Internal sensors connected to the temperature signal port are independent to the sensors used for temperature control.

> **CAUTION:** Installations of external sensors must be performed by CooperSurgical or by persons authorized by CooperSurgical only.

External Sensors

The following external sensors can be used with the G210 InviCell:

External CO_2: Cylindrical sensors between 11 and 25mm (e.g. Vaisala GMP251)

The CO_2 sensor needs to be purchased separately, direct from its supplier.

External Monitoring

A separate guide is available with details. Contact Customer service for a copy of the guide, which should be given to installers of any independent monitoring system.

Supplied Accessories for G210 InviCell

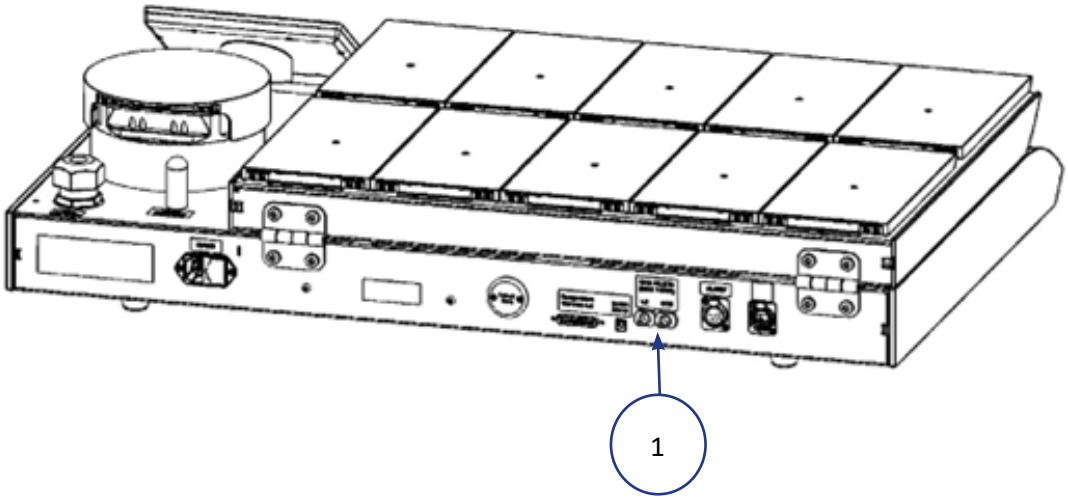
- Connector for GMP251 Carbon Dioxide Probe from Vaisala Oyj. Order code: K60017

CooperSurgical customers that choose to use 3rd party products and/or services in combination with CooperSurgical products are responsible for ensuring that the 3rd party product or service properly operates, performs and, when applicable, communicates with the CooperSurgical product. CooperSurgical takes no responsibility for 3rd party products or services not sold or provided by CooperSurgical.

SECTION 7 - SET-UP

Before use, see chapter “Section 9 - Settings”.

Gas Supply



1. The G210 InviCell is not supplied sterile and should be cleaned before use. Make sure the gas input ports at the back of the incubator are also cleaned. See “Section 12 - Maintenance” on page 42.
2. Install the ORIGIO Gas Line Filter, see “Replacing the ORIGIO Gas Line Filter” on page 48. This will normally be carried out by CooperSurgical service staff.
3. Connect the gas supply via the gas connectors (1) at the back of the unit.
4. Turn on the incubator.
5. Ensure the incubation temperature & gas concentrations are as required (within Setpoint menu). Also confirm gas control settings (Settings menu, then press Settings under the System heading). Allow 30 minutes for temperature and gas concentrations to stabilize. (see “Changing the Temperature Setpoint” on page 26).

WARNING: Use only pure CO_2 and pure N_2 gas. Use of other gases could result in serious injury. Make sure that gas supply pressures are kept between a minimum of 0.5 bar and a maximum of 1.0 bar.

Factory Settings

The G210 InviCell is supplied with the following factory settings.

Criteria	Setting
Temperature	37.0° C
Gas concentration	CO_2: 5.0% O_2: 5.0 %

Typical gas flow values at 5% CO_2 and N_2 and stable operation are 1.4l/h for CO_2 and 7l/h for N_2.

SECTION 8 - BASIC OPERATION

> **CAUTION:** Do not use the incubator if the alarm system of the device has issued a failure message and the cause of the failure has not been corrected.

It is important that the appropriate Dish Inserts are selected for the culture dishes used (LifeGlobal, Falcon, Nunc, Vitrolife) to ensure there is direct contact between the dish and the heated surface.

Dishes which present no opportunity for an air gap between dish and heated surface can be placed directly on the heated surface with no need for a Dish Insert.

The use of Dish Inserts requires temperature calibration with the Dish Insert in place (see "Dish Inserts" on page 5).

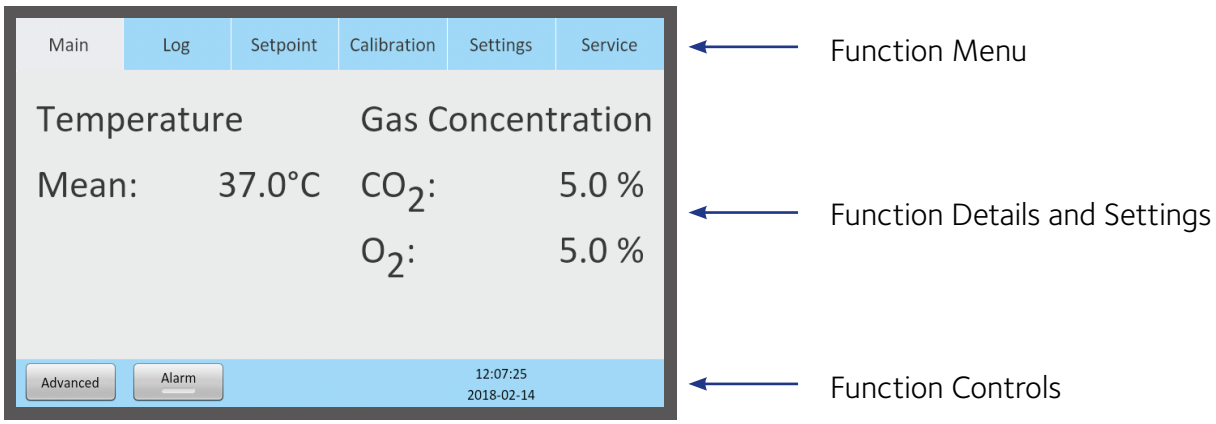
1. Place the Dish Inserts in the chamber and close the lid.
2. Wait 30 minutes for the Dish Inserts to heat up.
3. Open the chamber lid.
4. Place the culture dishes containing gametes or embryos on the Dish Inserts ensuring they are placed securely in the correct milled grooves.
5. Close the lid.
6. Enter the patient ID as per "Edit Chamber Information" on page 24.

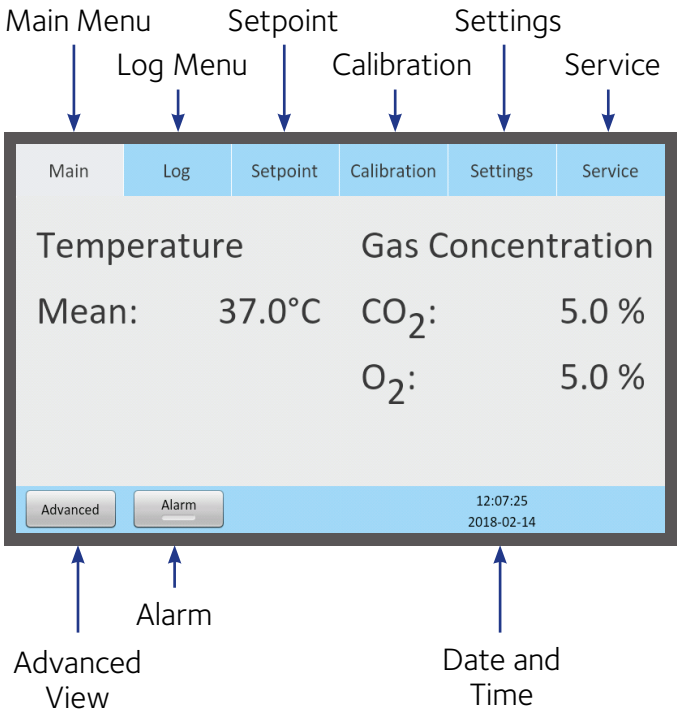
Touchscreen Menu

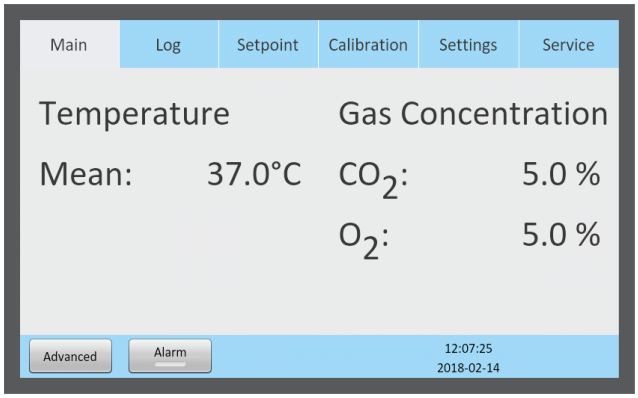
All the unit's functions and settings are controlled from the touchscreen.

When the power is connected the main screen will appear on the display.

The touchscreen can be operated with gloves.

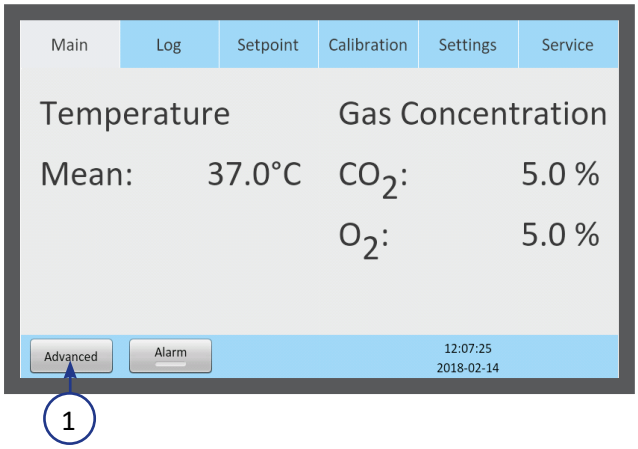






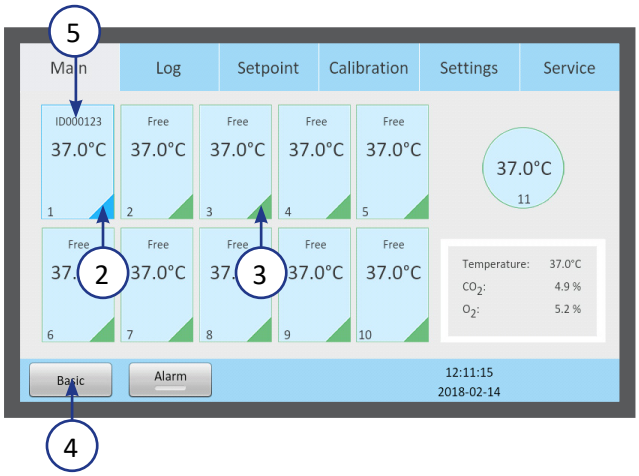
Main Menu

The main screen provides an overview of the temperature and gas concentrations inside the incubator.

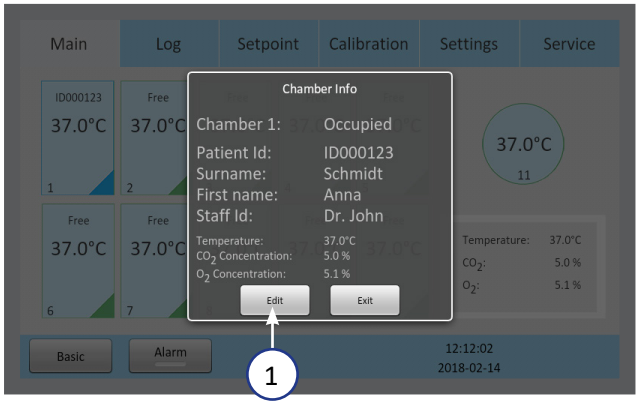


Advanced Menu

1. Press Advanced (1) in the main menu.

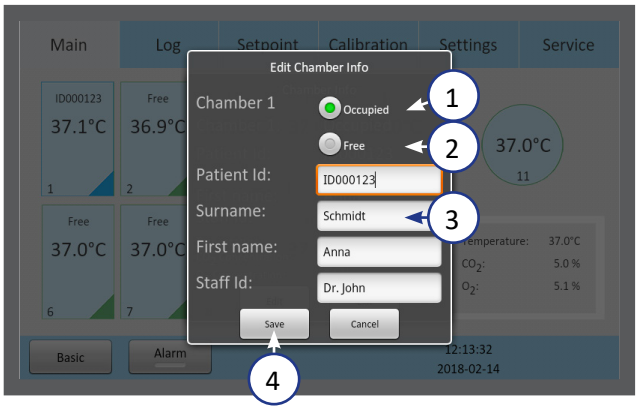


2. The advanced menu shows the temperature in each chamber.
3. Chambers that are marked with blue (2) are occupied, chambers marked green (3) are vacant.
4. To return to the main menu press Basic (4).
5. Patient ID (5).



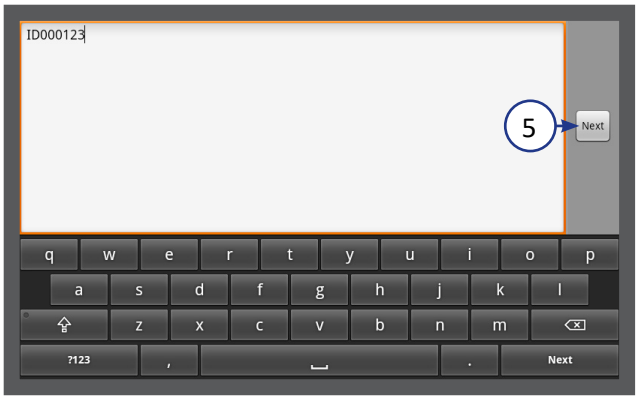
Chamber Information

1. Press a chamber to get information about its status.
2. The same information appears on the screen when a chamber lid is opened.
3. Press Edit (1) to edit chamber information.

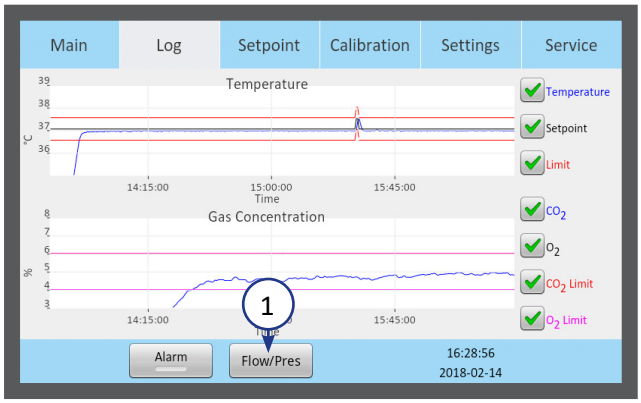


Edit Chamber Information

1. Press Occupied (1) and type in the text fields (3). When a text field is pressed, a keyboard appears on the screen.
2. All fields (Patient ID, Surname, First name and Staff ID) are limited to 10 characters.
3. Press Free (2) to leave the chamber vacant. Press Save (4).

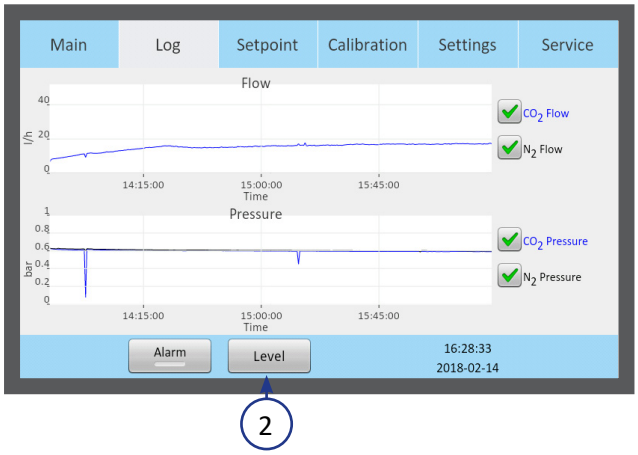


4. Press Next (5) to continue to the next step, if required.

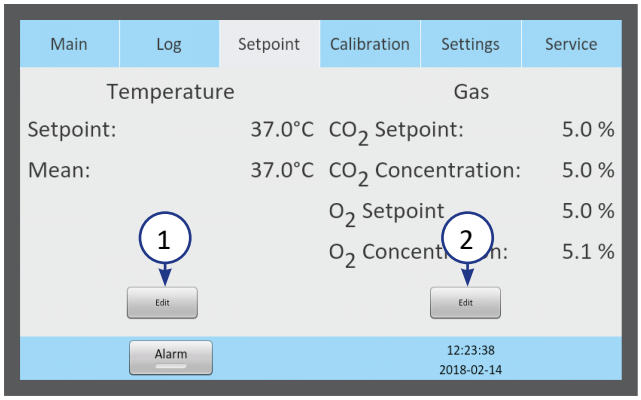


Log

1. The Log menu shows the temperature and gas concentration over a three hour period.
2. Press the Flow/Press button (1) to see gas flow and pressure (see below image) over a three hour period.

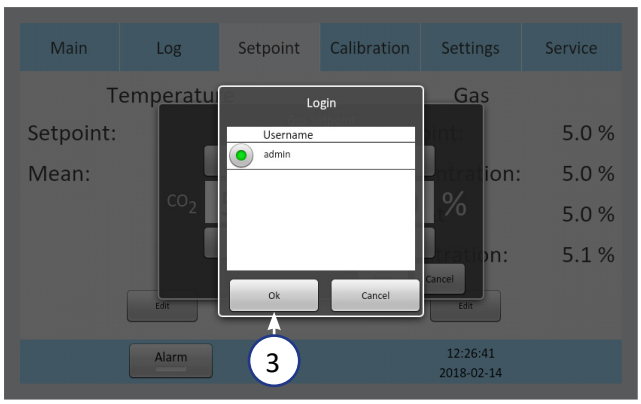


3. Press Level button (2) to return to temperature and gas concentration.

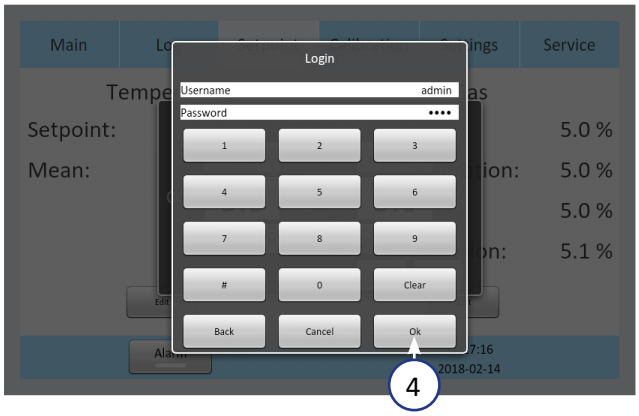


Setpoint

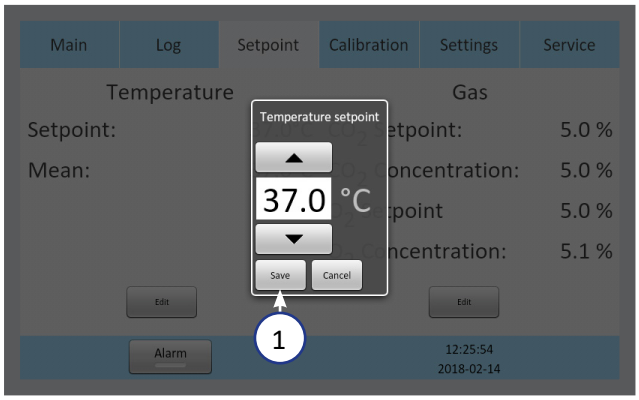
1. The Setpoint menu shows the setpoints for temperature and gas concentration. Press the Edit button for Temperature (1) or for Gas (2).



2. Only administrators and advanced users have access to change the setpoints. Select a user and press OK (3) .

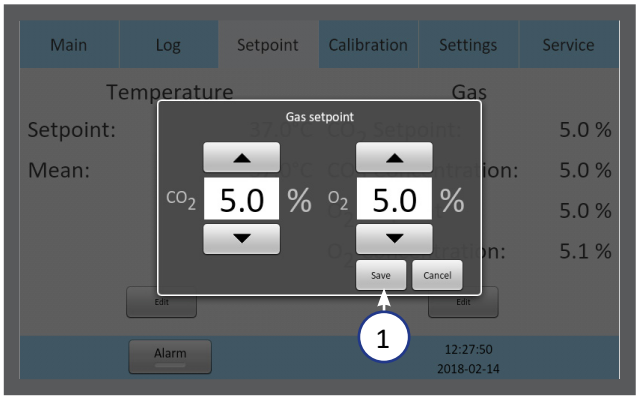


3. Enter the password and press OK (4).



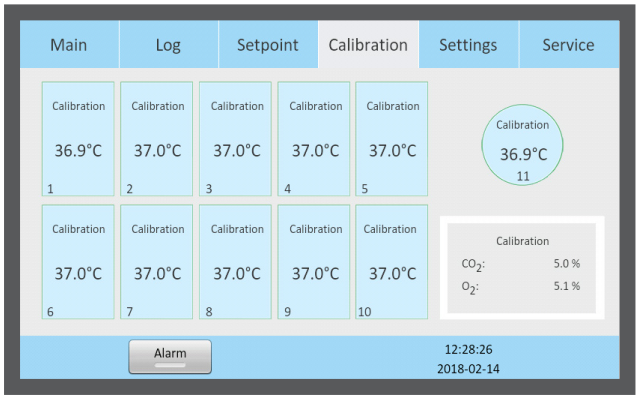
Changing the Temperature Setpoint

1. Adjust the temperature setpoint by pressing the arrow buttons. Press Save (1).



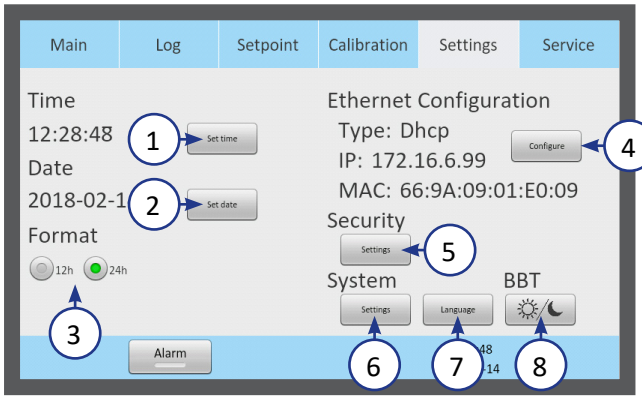
Changing the Gas Setpoint

1. Adjust the gas setpoint by pressing the arrow buttons. Press Save (1) .



2. It is recommended that gas concentrations are checked after changing the gas setpoint.

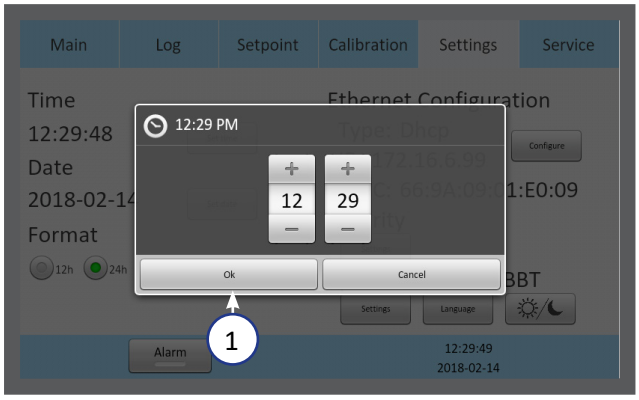
SECTION 9 - SETTINGS



The Settings menu shows:

1. Time settings (1)
2. Date settings (2)
3. Time format (3)
4. Ethernet configuration (4)
5. Security settings (5)
6. System settings (6)
7. Language (7)
8. Basal Body Temperature (BBT) settings (8)

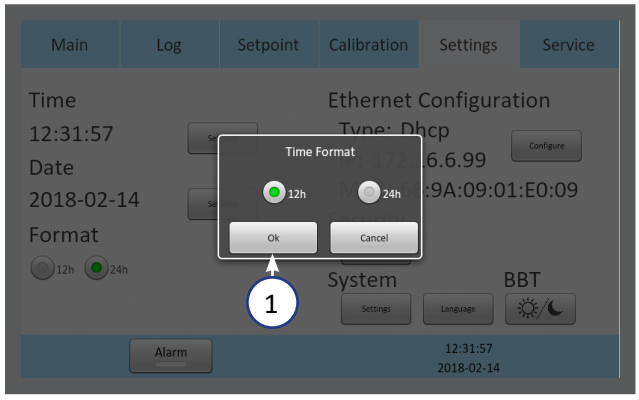
To change some of these settings requires a login (see “Security Settings” on page 29 and “Access Levels” on page 30).



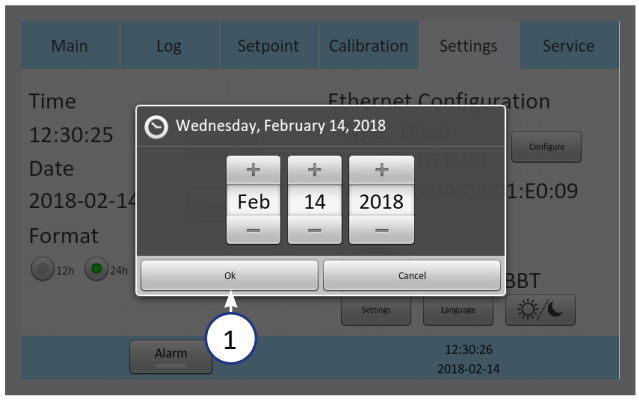
Changing the Date and Time

Select the date or time button

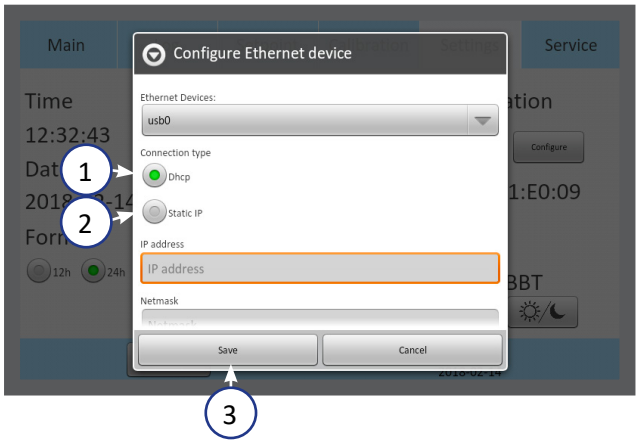
1. Adjust the time by pressing the + or -.
2. Press OK (1).



3. Select 12 or 24 hour time format.
4. Press OK (1).



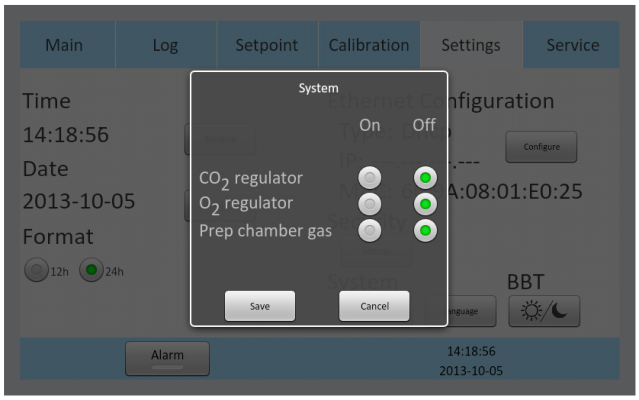
5. Adjust the date by pressing the + or -.
6. Press OK (1).



Ethernet Settings

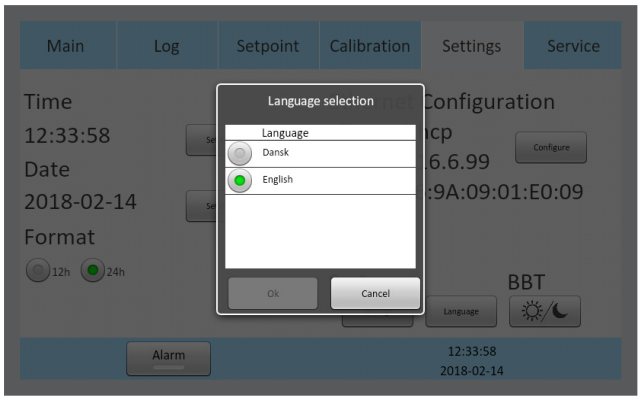
Select the Configure button from the settings menu. It is recommended to allocate a static IP address to the device. Consult an IT Specialist/Department for network settings.

1. Select DHCP (1), or
2. Static IP (2)
3. If static IP is selected, enter the settings provided by the IT department.
4. Press Save (3).



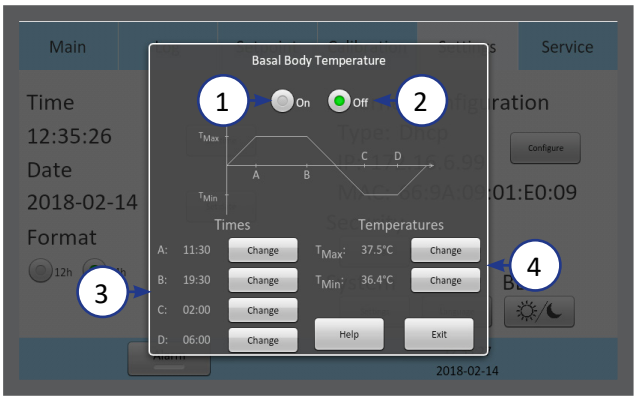
Changing the Gas Control Settings

Select the Settings button from the Settings menu (under the System heading). Changing CO_2 regulator, O_2 regulator and gas supply to the Preparation Chamber on or off.



Changing Language

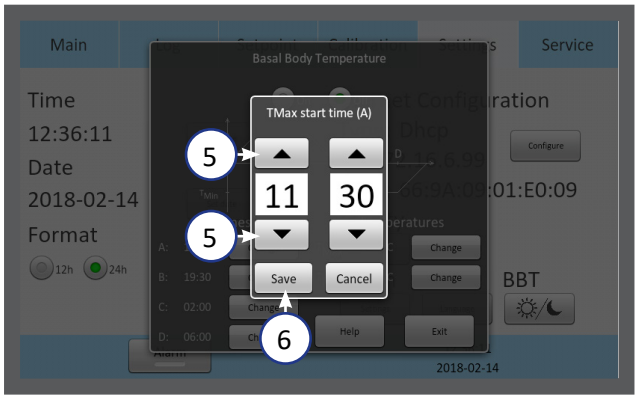
Select the Language button from the settings menu. Choose the preferred language in the language menu.



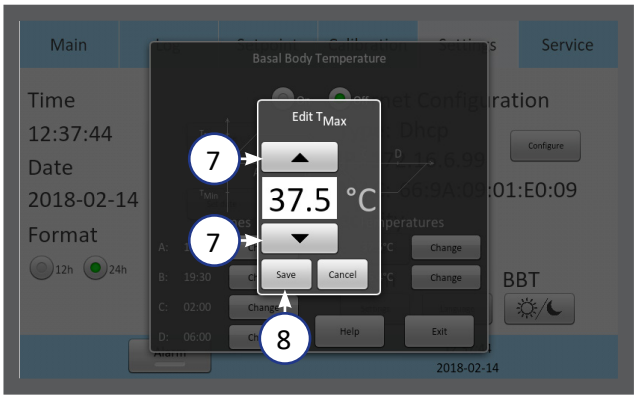
Changing Basal Body Temperature

Select the BBT button from the settings menu.

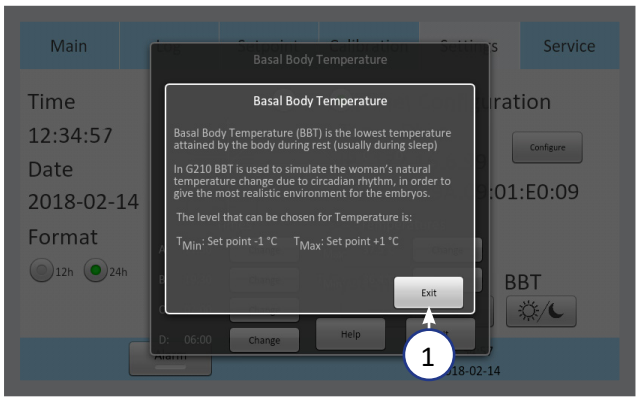
1. Turn the BBT on (1) or off (2)
2. Adjust the time (A, B, C and D) values (3).
3. Adjust the temperature T_{Max} and T_{Min} (4).



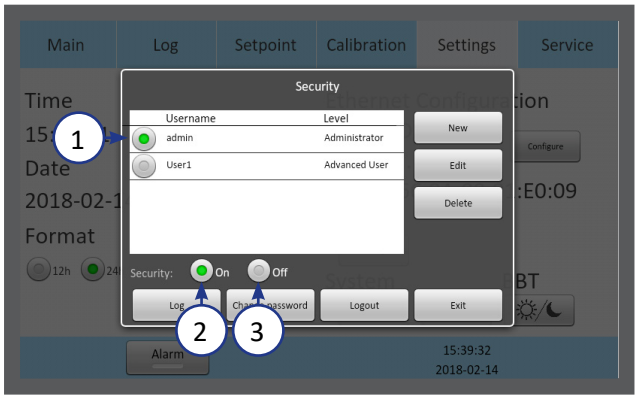
4. When BBT is activated the temperature in the setpoint menu cannot be changed.
5. Press one of the four time buttons (A, B, C or D). Adjust the time value by pressing the up and down arrows (5).
6. Adjust all four time values (3).
7. Press Save (6).



8. Adjust both the T_{Max} and the T_{Min} values by pressing the up and down arrows (7).
9. Press Save (8).



A short explanation of BBT is displayed by pressing the 'Help' button. Press Exit (1) to continue.



Security Settings

In order to prevent unauthorized changes to setup parameters, the unit uses different access levels.

In the security menu new users can be created and assigned access levels.

1. Select the Admin user (1) and turn the security on (2) or off (3).
2. The default password for admin is: 1234

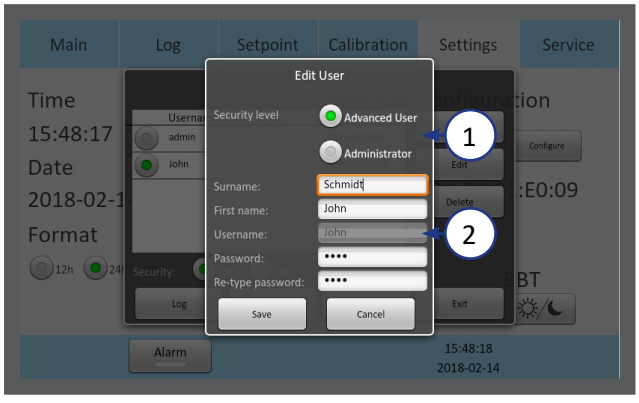
Access Levels

The unit supports three access levels: User, Administrator and Advanced User. Their characteristics are shown below:

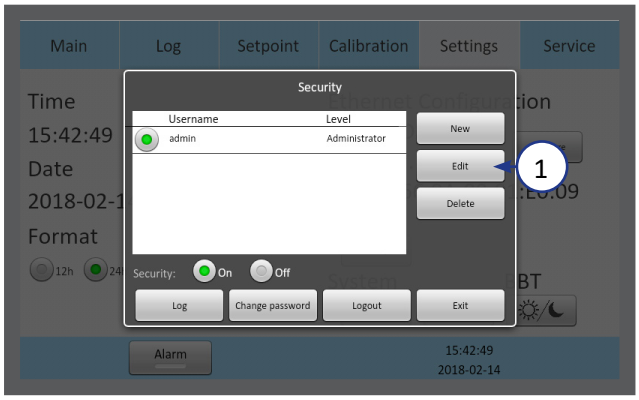
	User	Advanced User (login required)	Administrator (login required)
Changes that do not require login	✓	✓	✓
Change setpoint		✓	✓
Change settings		✓	✓
Change own password		✓	✓
Calibration			✓
Create new users			✓
Edit users			✓
Delete users			✓
Reset filter counter			✓

When attempting to change a parameter that requires authorisation, the login window will pop up on the touchscreen.

Leaving a topic that requires a login will automatically log the user out.

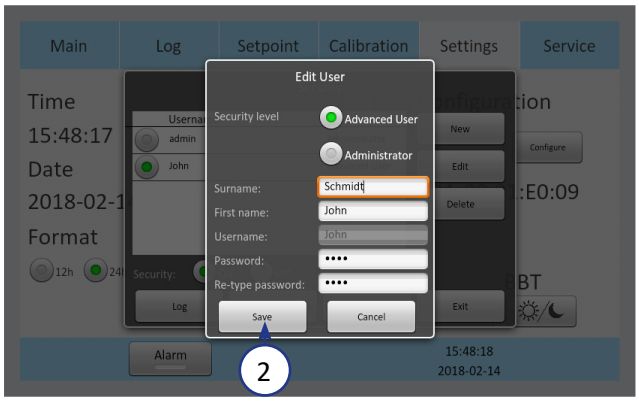


1. Select the access level for the user, Advanced User or Administrator (1)
2. Enter the user's data (2). There are 10 characters for Surname, First name and Username, and between 4 and 10 characters for the password.



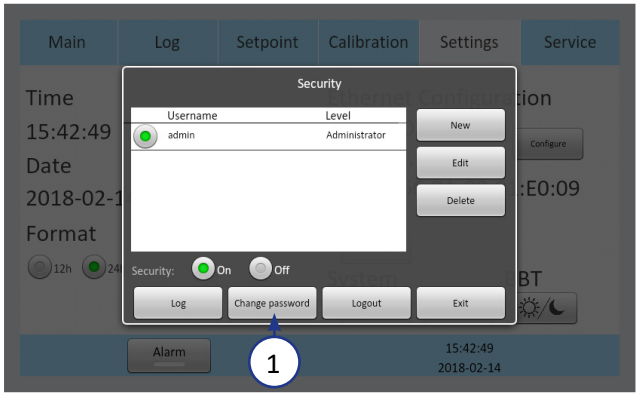
Edit User

1. Select a user in the Security window, and press Edit (1) .



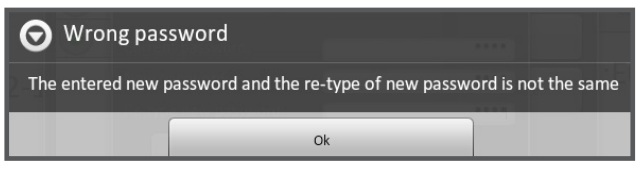
2. The access level, name and password can be edited here. Press Save (2) when done.

Change Password

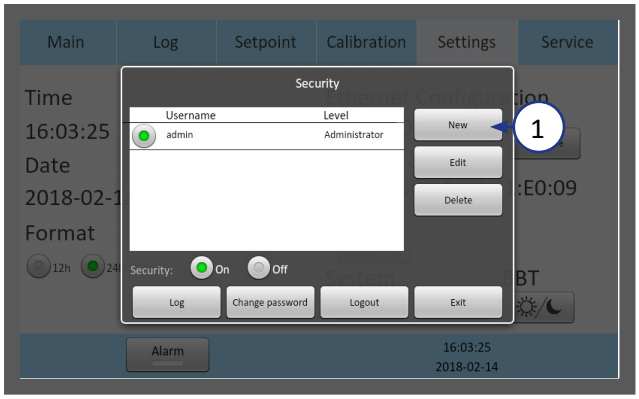


1. Press Change password (1) to change the admin password.

2. Enter the current password (2). Enter the new password twice (3).
3. The password must be between 4 and 10 characters long.
4. Press OK (4).

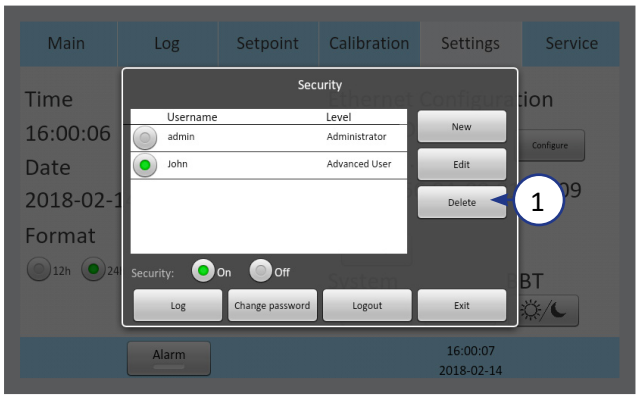


5. If an incorrect password is entered twice these warnings appear.



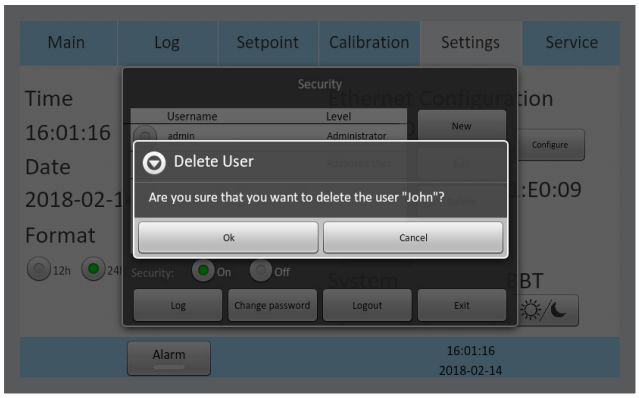
Create a New User

1. In the security window, press New (1).

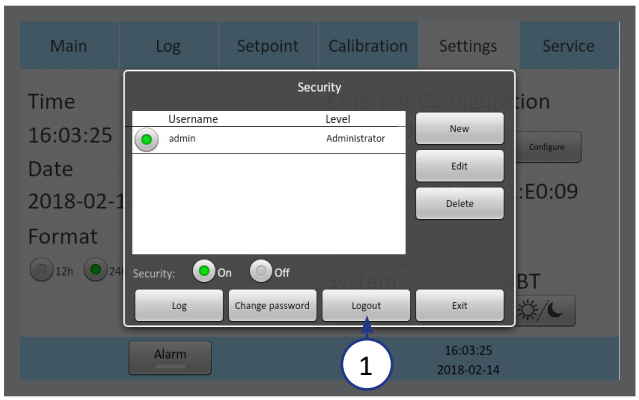


Delete User

1. Select a user in the security window, and press Delete (1).
2. It is not possible to delete the “admin” user.



3. Confirm ‘OK’ to delete a user.



Log Out

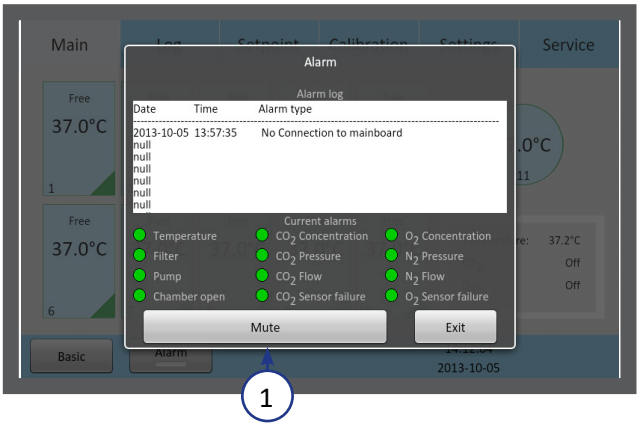
1. In the Security window press Logout (1).
2. Administrators or Advanced Users will be automatically logged out after 5 minutes of inactivity.

Lost Password

If all Administrator passwords are lost, please contact a sales representative or local distributor to acquire a special login. Please have the unit’s serial number at hand, as the special login is unit specific.

Alarm

A flashing red light alarm button indicates that an alarm has been activated. An audible alarm will also be activated. Press the alarm button to open the alarm message box.

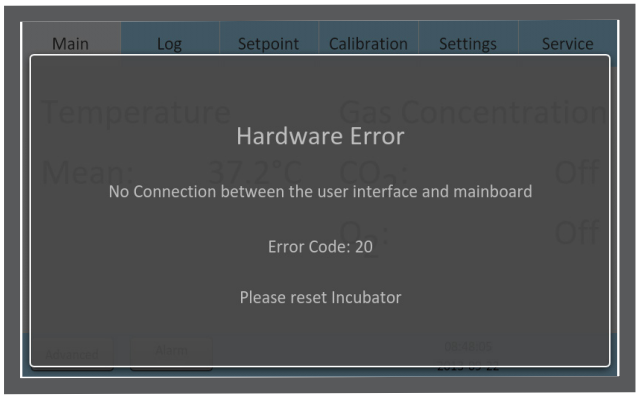


The alarm box shows information about the current alarm. Press Mute (1) to turn off the audible alarm.

The alarm will be activated:

- If the chamber temperature is too high or too low.
- If the gas concentrations are too high or too low.
- If there is a CO_2 or O_2 sensor failure.
- When there is a hardware error.

The unit is equipped with an external alarm connector which can be connected to a monitoring device. The connector can be connected to either a voltage source or a current source.



Errors

In the case of a hardware error, a message and an error code will be shown.

For more information about alarms, see “Section 11 - Troubleshooting” on page 40.

CAUTION: Do not use the incubator if an alarm is triggered and the cause of the failure has not been corrected.

SECTION 10 - K-LINK

K-Link software can be used to communicate with a G210 InviCell over a TCP/IP network to retrieve, display and save a log of measurements, warnings, and daily averages into a spreadsheet. K-Link can also be configured to send email notifications when alarms are triggered.

Starting K-Link

To launch the K-Link software, double click on the K-Link icon on the desktop or in the start menu.

NOTE: In order modify settings in K-Link such as adding a new device to the Device Connection list, or modifying email configuration settings, K-Link must be launched with elevated administrative privileges.

To launch K-Link with elevated administrative privileges, right-click on the K-Link icon, then click "Run as administrator". There may be a prompt to enter alternative credentials. Consult your IT Department for further details.

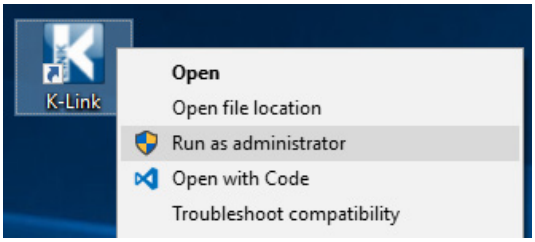


Figure 10-1

Figure 10-2

The K-Link loading screen is displayed for a few seconds while the software loads.

Device Connection

The device connection screen displays a list of previously saved devices to load.

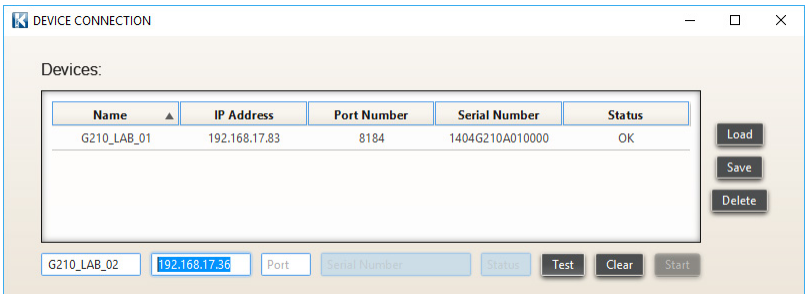


Figure 10-3

A new device can be added to this list by entering its IP address, then after performing a successful connection test, pressing "Save".

After loading a device, and performing a successful connectivity test, indicated by status "OK", logging can be started by pressing "Start".

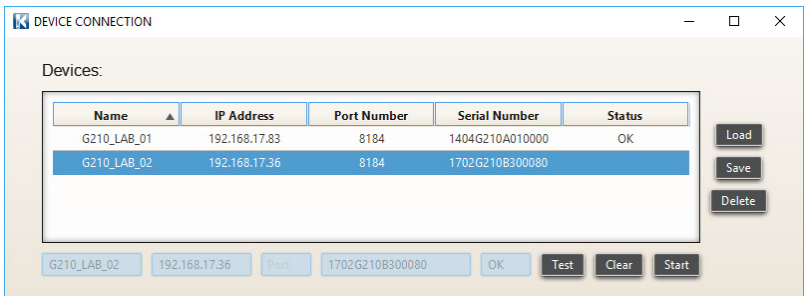


Figure 10-4

NOTE: Ensure that the system time of the computer running the K-Link software and the system time of the G210 InviCell have both been set to the correct time before proceeding.

NOTE: To ensure a stable connection between K-Link and the G210 InviCell, it is recommended that the G210 InviCell be configured with a static IP address. Consult your IT department for IP configuration settings specific to the network being used.

NOTE: After pressing "Start", the device connection window will disappear, and the main window will appear. However, it can take up to 1 minute before any graph can be seen.

Measurement Section

The measurement section displays the measurements retrieved from the device every 30 seconds, the connection status of the device, a setting to enable or disable email notifications if an alarm is triggered, and an "Open Log" button to explore the folder containing the file where the logs are being saved.

Figure 10-5

Alarm Display Section

The alarm section displays the status of the alarms. When an alarm is activated on the device, the associated alarm in K-Link will change colour to red. When the alarm is no longer activated on the device, the associated alarm in K-Link will change colour back to green. K-Link refreshes the alarms every 5 seconds.

Figure 10-6

Graph Section

The graphs displayed will automatically scale to fit the measurements however the Y-Axis can be adjusted by holding down the left mouse button and “dragging” a box around an area of interest then releasing the button. A single left-click anywhere on the graph will reset to the original scale.

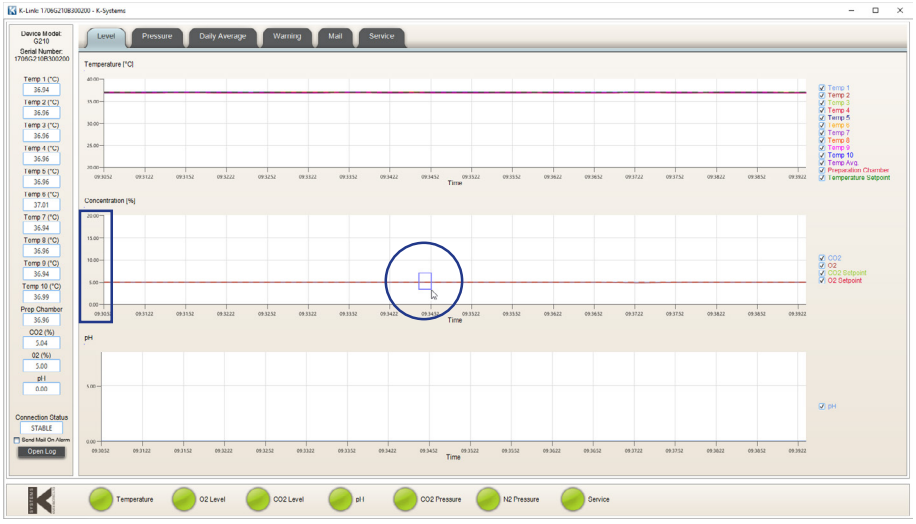


Figure 10-7

Figure 10-8

10

Level Tab

The Level tab displays a graph of the gas concentration levels over time.

Figure 10-9

Pressure Tab

The Pressure tab displays a graph of the device measurements over time.

Figure 10-10

Daily Average Tab

The Daily Average tab displays daily averages for the individual measurements collected from the device every 24 hours.

Figure 10-11

Warning Tab

The Warning tab displays information about the last 50 individual alarms.

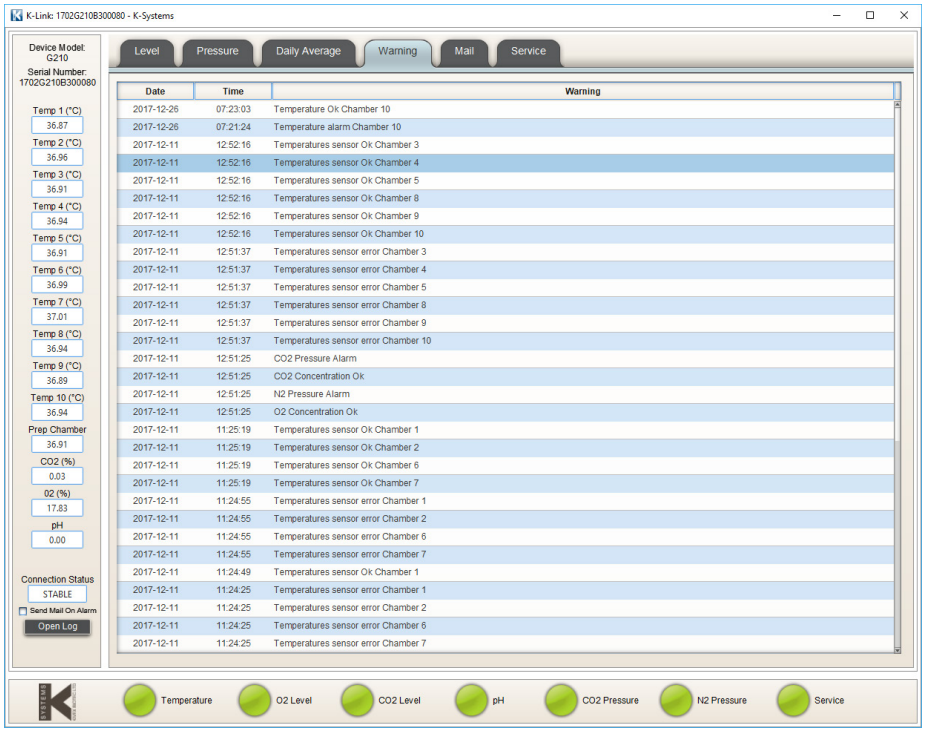


Figure 10-12

Mail Tab

The Mail tab allows users to configure K-Link to email notifications about alarms and service information.

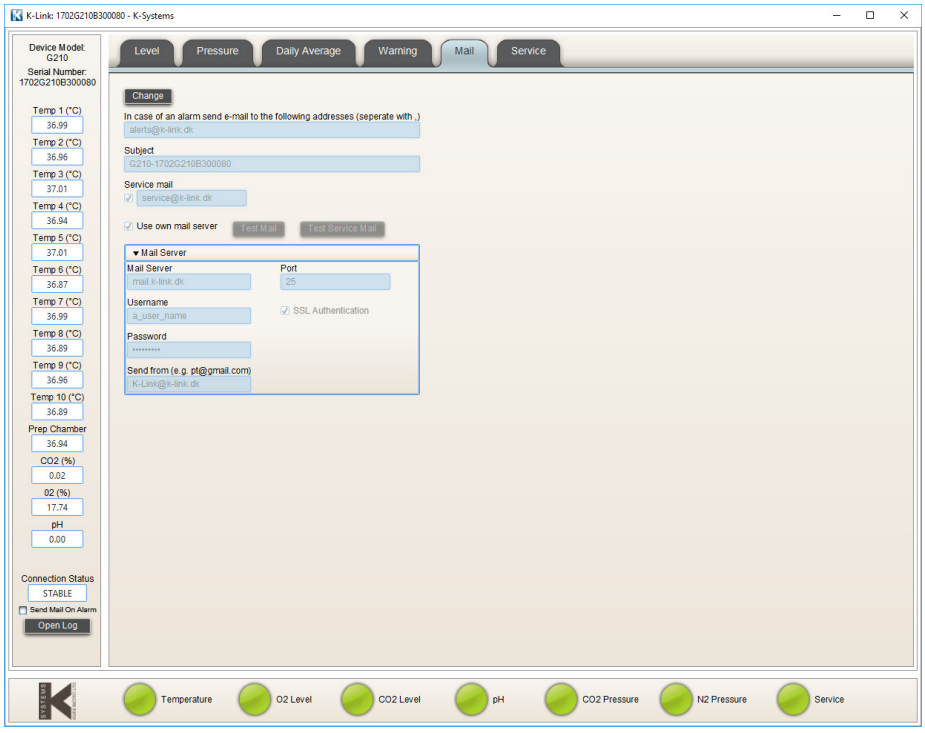


Figure 10-13

Note: It is recommended to configure K-Link to a specified mail server. Consult your IT Department for mail server information.

Service Tab

The service tab presents software versioning information, device connectivity and serial number information. It also shows counters to indicate when a general service check, a filter change should be conducted. When the counters time out, the service alarm light is triggered and will remain active until all counters are reset. K-Link refreshes information displayed in the service tab every 10 minutes.

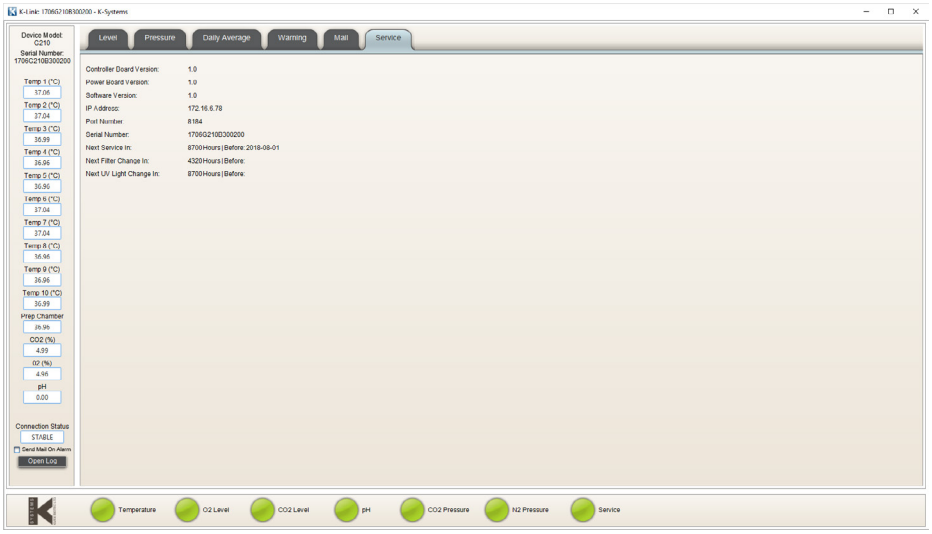


Figure 10-14

SECTION 11 - TROUBLESHOOTING

Heating System

Symptom	Cause	Action
Wrong temperature and the alarm is on	The temperature has not stabilized within 0.5 °C of the setpoint.	Ensure all lids are closed and wait for the temperature to stabilize.
Wrong temperature on touchscreen after system has had time to stabilize	The setpoint for temperature is wrong	Check the setpoint temperature and adjust to the required temperature.
Temperature differs between chambers	System not properly calibrated	Calibrate each chamber using a high precision thermometer

CO_2 Gas Regulator

Symptom	Cause	Action
Wrong CO_2 level measured at sample port	System not powered on	Check mains and main fuse
	CO_2 gas regulator is OFF	Activate CO_2 gas regulator
	No CO_2 or wrong gas attached to CO_2 gas input	Check gas supply, make sure that 0.5-1.0 bar of gas pressure is applied
	Actual gas concentration is higher or lower than setpoint	Check CO_2 setpoint and adjust to the required concentration
	Actual gas concentration is higher or lower than setpoint	Recalibrate the gas concentration
Poor CO_2 gas regulation	Lid(s) are left open	Close lid(s)
	Seals are damaged or missing on lid(s)	Check the seals are intact
CO_2 concentration alarm	CO_2 gas concentration more than ± 1% from setpoint	Allow system to stabilize by closing all lids
CO_2 pressure alarm	No/wrong CO_2 gas pressure to system	Check CO_2 gas supply; make sure that pressure is kept stable at 0.5-1.0 bar

O_2 Gas Regulator

Symptom	Cause	Action
Wrong O_2 level measured at sample port	System not powered on	Check mains and main fuse
	O_2 gas regulator is off	Activate O_2 gas regulator
	No N_2 or wrong gas type attached to N_2 gas input	Check gas supply; make sure that 0.5-1.0 bar of N_2 gas is applied
	Actual gas concentration is higher or lower than setpoint	Check O_2 setpoint
	Actual gas concentration is higher or lower than setpoint	Calibration of the gas concentration is needed

Symptom	Cause	Action
Poor O_2 gas regulation	Lid(s) are left open	Close lid(s)
	Seals are damaged or missing on lid(s)	Check the seals are intact
O_2 Concentration alarm	O_2 gas concentration more than ±1% from setpoint	Allow system to stabilize by closing all lids
O_2 Pressure alarm	No/wrong N_2 gas pressure to system	Check N_2 gas supply, make sure that pressure is stable at 0.5-1.0 bar. If O_2 regulation is not needed, set the O_2 regulator to OFF in the menu to deactivate oxygen regulation and abort the N_2 alarm

Gas Consumption

Symptom	Cause	Action
Gas consumption too high - typically above • 20 l/h for N_2 • 5l/h for CO_2	A coupling has not been removed from the sample port	Remove the coupling and replace the protection cap
	The sample connector has not been fully released	Press down the ejector ring on the connector to close the sample port
CO_2 is decreasing and O_2 is increasing during gas sampling.	G210 InviCell is emptied of gas	Turn off G210. InviCell Restart the G210 InviCell.Let gasses stabilize, Check the N_2 and CO_2 gas supply is connected and the pressure is stable at 0.5-1.0 bar
Wrong gas concentration in one chamber	Lid plug has been penetrated more the 5 times, allowing gas to escape.	Replace lid plug

Touchscreen

Symptom	Cause	Action
Absent or erratic function of operation buttons	Failure in the touchscreen	Contact the service representative. Touchscreen replacement may be required.
Missing pixel in touchscreen	Failure in the LED screen	Contact the service representative. Touchscreen replacement may be required.
Repeat closure and opening of Android screen	Inconsistency between the date and time on Android and PC	Synchronize date and time on G210 InviCell and PC. Restart K-Link.

SECTION 12 - MAINTENANCE

Periodic cleaning is recommended as part of routine maintenance. Disinfection is also recommended for media spills, visual accumulation of dust, and other evidence of contamination.

Clean and disinfect the G210 InviCell and, when necessary, sterilize the Dish Inserts immediately after any media spills.

Cleaning and disinfection should be performed with no samples inside the incubator and the incubator switched off.

Gloves should be worn during cleaning, disinfecting and sterilizing.

Preparation at the Point of Use

After every patient procedure, wipe down the incubator immediately after use to prevent soil from drying on the device by performing the following steps:

1. Moisten a clean lint-free cloth with warm tap water (38°C to 49°C)
2. Use the moistened clean, lint-free cloth and wipe off any visible soil.

Periodic Cleaning

1. Apply a laboratory detergent evenly to all surfaces using a sterile cloth. Note: use a minimal amount of detergent on a damp cloth. Liquids entering the gas ports can cause damage to the product.
2. Moisten a sterile non-linting cloth with purified or sterile water and wipe all surfaces for a minimum of one (1) minute per chamber. If needed, use additional cloths if cloths become visibly soiled.
3. Allow chamber to air dry.
4. Visually inspect each chamber for the absence or presence of remaining soil. While inspecting, give particular attention to verifying soil has been removed from the hard-to-clean areas. If soil is present, then repeat the manual cleaning steps until all visible soil is removed.

Disinfection

1. After the incubator is clean and all visual soil has been removed, to disinfect the incubator as follows:
2. Apply disinfectant evenly to all internal and external surfaces of the chambers and lids.
3. Moisten a sterile non-linting cloth with purified or sterile water and wipe all disinfected surfaces for a minimum of one (1) minute per chamber.

Drying

Thoroughly dry all surfaces of the incubator using a sterile, lint-free wipe or cloth, changing wipes/ cloths when necessary to ensure the incubator surfaces are completely dry. Visually inspect the surfaces of the incubator to ensure all surfaces are clean and dry. Repeating drying steps if any moisture is visible.

Sterilizing the Dish Inserts

Use this procedure in cases of contamination and/or spillage:

Packaging:

1. Promptly soak up excess liquid using a sterile cloth.
2. Remove the Dish Insert from the incubator chamber.
3. Moisten a sterile cloth with sterile water and wipe all surfaces, especially all of the milled grooves.
4. Wrap Dish Inserts in a breathable sterilization wrap or place in a sterilization pouch in accordance with local procedures. In the United States (US), use an FDA-cleared sterilisation wrap or sterilization pouch.

Steam Sterilization:

5. Use a validated, properly maintained and calibrated steam sterilizer.
6. Effective steam sterilization can be achieved using the following cycle:

Cycle Type	Minimum Temperature	Minimum Exposure Time / Dry Time
Gravity	121 °C (250 °F)	30 minutes / 30 minutes dry time

For further guidance for Sterilization, refer to: ANSI/AAMI ST79 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities."

Validation Check

Perform the following validation gas and temperature checks after all cleaning, disinfecting and sterilizing or at least every two weeks to ensure the G210 InviCell is operating correctly.

Gas Calibration

It is very important that the G210 InviCell is not emptied of gas during the gas calibration procedure. To do so will cause unstable gas levels and gas flow and will result in a considerable time before the gas concentration is recovered and becomes reliable and stable again.

To ensure the G210 InviCell is not emptied of gas during the gas sampling please follow the below instructions.

There are two methods for collecting gas samples from the incubator.

1. Via the Gas Sample Port (located behind the Preparation Chamber, and connected directly to the internal gas mixing chamber)
2. Via the silicone plug on each of the chamber lids

Always check the gas concentration in the setpoint menu during sampling. If the gas concentration differs more than 0.1% from the setpoint, allow the G210 InviCell to stabilize to the gas concentration set point before taking the next gas sample.

Allow 2 minutes between samples to allow the incubator to stabilize.

Please Note: To ensure accurate and reliable gas measurements, please use a high-quality

calibrated gas analyzer. The calibration procedure described here assumes the use of the G100 gas analyzer (Order Code: 11103).

Ensure the gas analyzer is prepared as per the gas analyzer user manual.

Gas flow to the Preparation Chamber should be switched off during gas calibration. (See page 28, Changing the Gas Control Settings).

Gas Calibration Procedure

1. Connect a length of tubing to the gas analyzer input.
2. Connect the coupler (K59688) from the supplied accessories to the tubing.
3. Remove the protection cap from the sample port. (1)

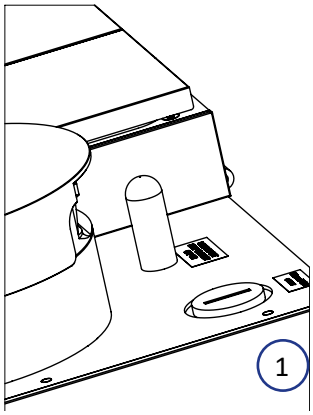


Figure 12-1

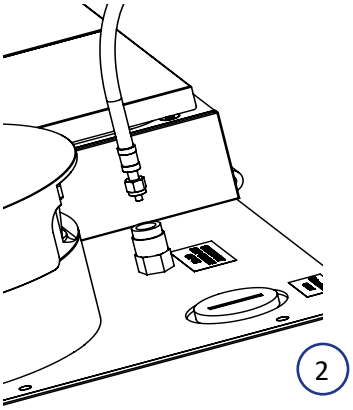


Figure 12-2

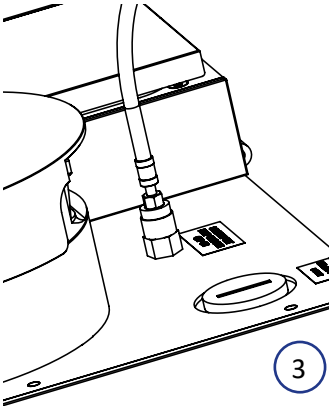


Figure 12-3

4. Connect the coupling to the sample port. (2) & (3)
5. Collect the gas sample using the gas analyzer. **Note:** wait at least 30 minutes after powering on the G210 InviCell, or after any change to gas concentration settings within Setpoint tab or Calibration tab prior to taking the gas sample.
6. Stop the gas analyzer pump.
7. Record the gas concentration reading.
8. Disconnect the coupling from the sample port.
9. Replace the protection cap.

If calibration is needed, adjust the value on the calibration, wait for the gas to stabilize and re-test.

After calibration the gas flow to the Preparation Chamber can now be switched back on. (See page 28).

Chamber Lid Plug

A silicone plug is placed in the lid of each chamber. For collecting a gas sample, penetrate the lid plug with a needle attached to tubing and connect to the gas analyzer input. Do not use needles larger than 0.5mm x 25mm. The angle for penetration should be vertical (+/- 10 degrees) and no horizontal movements should be made. Each plug should not be penetrated more than 5 times after which it should be replaced.

Verification of Gas Concentration in Chambers

1. Connect a short length of tubing to the gas analyzer input.
2. Connect a 25-gauge needle to the tubing.
3. Penetrate the required chamber through the silicone plug.
4. Collect the gas sample using the gas analyzer.
5. Stop the gas analyzer pump.
6. Remove the needle from the silicone plug.
7. Record the gas concentration reading.
8. Wait 2 minutes between chamber sampling.
9. Repeat for the remaining chambers in the order shown below.

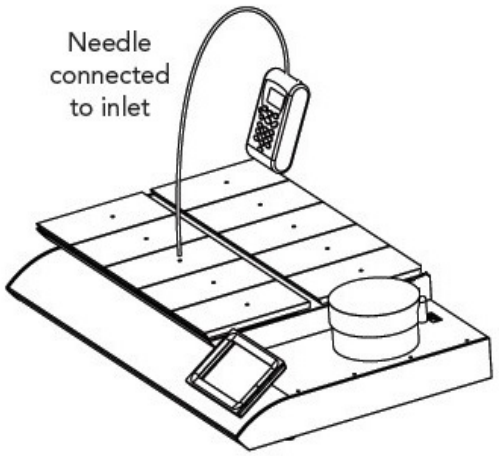


Figure 12-4

Order of sampling

1st. Chamber #8
2nd. Chamber #3
3rd. Chamber #7
4th. Chamber #2
5th. Chamber #9
6th. Chamber #4
7th. Chamber #6
8th. Chamber #1
9th. Chamber #10
10th. Chamber # 5

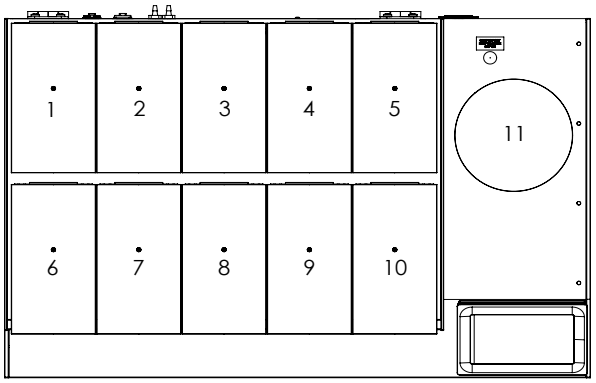


Figure 12-5

10. Take the average value for O_2 concentrations in the chamber with the highest and lowest O_2 concentration and change the calibration setpoint according to this value.
11. Take the average CO_2 concentrations in the chamber with the highest and lowest CO_2 concentration and change the calibration setpoint according to this value.
12. If a chamber is more than +/- 0.5 from gas setpoint, please contact a local Service Technician.

Temperature Calibration

Temperature calibration can be performed when a calibrated temperature sensor is inserted into each chamber as described in this section. To maintain a stable temperature and to prevent ambient air from entering the chamber, it is important to use a temperature sensor with a flat cable allowing the chamber lid to be closed during calibration.

CooperSurgical recommends the F100 Precision Thermometer together with the Solid Temperature Sensor for temperature calibration. If the calibration is not performed with the K-Systems Solid Temperature Sensor, CooperSurgical cannot guarantee correct calibration of the device.

NOTE: The sensor and thermometer should be calibrated as a unit and only by an accredited test house.

Temperature Calibration Procedure

1. Open the lid and place the calibrated temperature sensor at the bottom of the chamber.
2. If the chamber is used with a dish insert, place the sensor on the dish insert.
3. Close the lid.
4. Read the temperature when the temperature reading on the external thermometer is stable to the second decimal. **Note:** Wait 30 minutes after the initial switch on, or after any change to temperature settings within Setpoint tab or Calibration tab prior to reading the temperature.
5. Adjust the calibration setpoint by pressing the icon representing the requested chamber. See “Changing the Temperature Setpoint” on page 26.
6. Adjust the temperature calibration zone setpoint by pressing the arrows, until the temperature of the calibration zone setpoint correspond to the temperature reading. See “Changing the Temperature Setpoint” on page 26.
7. Wait until the temperature shown on the current chamber has reached the setpoint.
8. Repeat steps 4 and 5 until the required temperature is reached in the actual chamber.
9. Repeat steps 1 to 7 for all chambers.

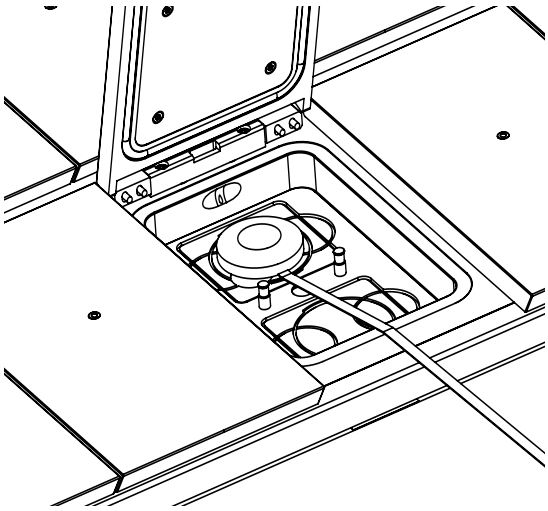


Figure 12-6

NOTE: Use only recommended thermometer and temperature probe equipment.

SECTION 13 – SERVICE

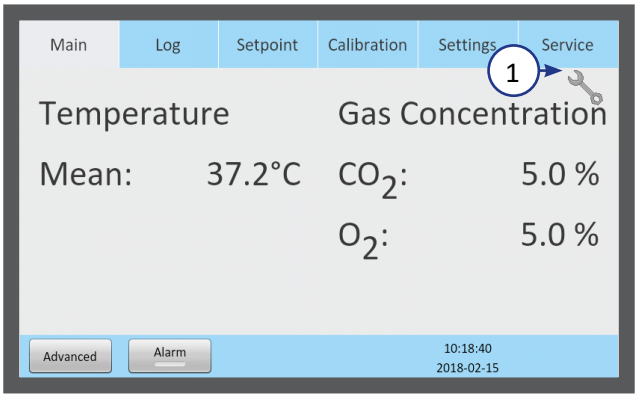
WARNING: DO NOT disassemble or modify any part of the G210 InviCell.

For the reliable and safe operation of this incubator it is strongly recommended that inspections and services are performed as stated in the Service Plan below. Failing to follow this plan may cause the unit to stop performing as intended and cause damage to embryos, blastocysts etc. kept inside the incubator.

Service plan

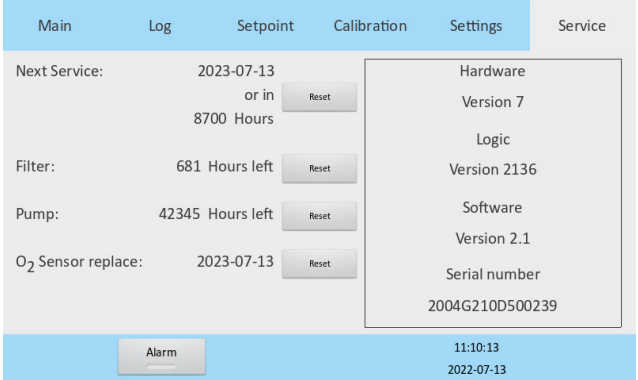
Conducted by	User	Authorized Service Representative		
Component name	**Every 3 months**	**Every year**	**Every 3 years**	**Every 6 years**
Replace ORIGIO Gas Line Filter	X			
Replace HEPA Inline Filter for CO_2 gas		X		
Replace HEPA Inline Filter for N_2 gas		X		
Replace O_2 sensor*		X		
Temperature and gas calibration		X		
Replace Pump			X	
Replace CO_2 sensor*				X
Replace Android battery			X	

*Gas calibration should be performed after replacing O_2 and CO_2 sensors.



On-screen Prompts

The service symbol (1) appears in the main screen when it's time for a service.



The Service menu shows when the unit's individual parts need to be serviced (2).

This screen (3) also displays hardware and software versions currently installed and the unit's serial number.

Replacing the ORIGIO Gas Line Filter

Remove all samples from the chambers before replacing the filters.

1. To access to the filter compartment, push the safety lock lever (1) and lift the upper part of the incubator containing the chambers.

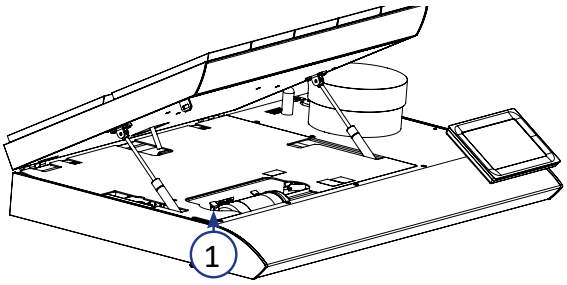


Figure 13-1

2. Pull the filter out of the holder and remove the connectors from each end. Fasten the connectors to the inlet and outlet of the ORIGIO Gas Line Filter (2).

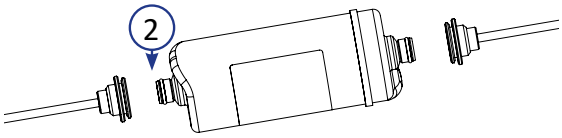


Figure 13-2

3. Ensure the direction of flow shown on the new ORIGIO Gas Line Filter label (3) is consistent with the flow direction (4) shown inside the filter compartment.
4. Place the ORIGIO Gas Line Filter in the filter holder with the label facing up (5).
5. Lower the upper part of the incubator.

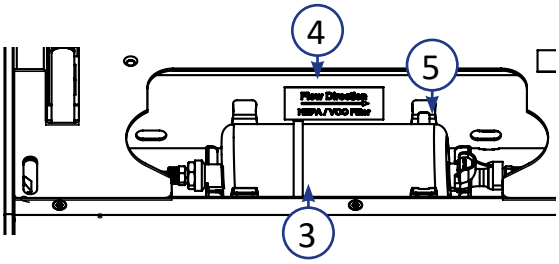


Figure 13-3

CAUTION: Do not use the unit without a genuine ORIGIO Gas Line Filter.

CAUTION: Insert filter with the filter label facing up. If the filter is not placed correctly, it can cause excessive gas consumption.

Disposal of the Gas Line Filter

CAUTION: Contamination Hazard

As the filter may have been used for processing and treating infectious substances, it might be contaminated. The used Gas Line Filter should be placed in a sealed plastic bag and labeled as biohazard material, then disposed of according to local requirements.

SECTION 14 - DISPOSAL AND RECYCLING

Information on recycling and handling of the unit as per the WEEE Directive (Waste Electrical and Electronic Equipment).

CAUTION: Contamination Hazard

As this device may have been used for processing and treating infectious substances, it might be contaminated. Prior to disposal, the whole device must be disinfected.

Environmental Protection for Disposal of the Product

The unit contains reusable materials. All components (with the exception of the ORIGIO Gas Line Filter) can be discarded as electrical waste after cleaning and disinfection.

Please note that ORIGIO Gas Line Filters must be discarded in accordance with the applicable national regulations for special solid waste.

CooperSurgical have taken the necessary steps to comply with the EC directive 2012/19/EU on waste electrical and electronic equipment (WEEE).

Environmental implications: WEEE contains materials that are potentially hazardous to the environment and to human health. Therefore, when this instrument has reached its end of life it must be collected and recycled separately from other waste according to national requirements. Please contact a local CooperSurgical distributor for instructions. Do not dispose of with 'normal' waste.

The following table provides information on the recycling and handling of the product in accordance with the WEEE Directive:

Recyclable Components

Component	Material
Lids	Aluminium
Exterior housing	Mild Steel, Aluminium, Stainless Steel
Interior housing	Aluminium and POM
Printed circuit board	Enclosed electronic components mounted on a PCB

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SECTION 15 - WARRANTY INFORMATION AND LIMITS ON LIABILITY

CooperSurgical warrants that this item will be free from defects in materials and workmanship for one year from the date of installation. If CooperSurgical determines that the product fails to conform to that warranty during the one-year period, CooperSurgical will repair or replace the product, at CooperSurgical's discretion, free of charge.

To return the product to CooperSurgical, a customer must comply with CooperSurgical's Returned Goods Policy described in this manual and the warranty requires the customer to return the product to CooperSurgical in accordance with the CooperSurgical Returns Instruction. CooperSurgical will return products (that it repaired or replaced under warranty) to the same customer who returned those products, at CooperSurgical's expense F.O.B. the customer's facility. Under all other circumstances, CooperSurgical will return products to the same customer who returned those products at the customer's expense.

CooperSurgical's warranties do not cover damage caused by misuse, improper care, improper use of chemicals or cleaning methods, loss, theft, use of non-authorized parts, servicing by non-authorized personnel or negligent or intentional conduct on the part of the owner or user of the product, nor do they cover normal wear and tear or general maintenance. Any modifications or changes to a product will void that product's warranty. CooperSurgical's warranties do not apply to any single-or-limiteduse, disposable or consumable components or items.

CooperSurgical is not responsible for, and the owner and operator of the product shall defend, indemnify and hold harmless CooperSurgical from and against, all claims, damages, and other losses resulting from the improper servicing, maintenance, repair, use or operation of the product or the owner or operator's negligence or willful misconduct, and use of inadequate packing and packaging when returning product for repair.

The above warranties are in lieu of, and CooperSurgical hereby disclaims, all other warranties, express or implied, written or oral, with respect to CooperSurgical products, including the warranties of merchantability and fitness for a particular purpose. No terms, conditions, understandings or agreements that purport to modify the above warranties or that make any additional warranties for any CooperSurgical product shall have any legal effect unless made in writing and signed by an authorized CooperSurgical corporate officer.

CooperSurgical shall not under any circumstances be liable for lost profits, damages from loss of use or lost data, or indirect, special, incidental or consequential damages under its warranties or otherwise for any claim related to CooperSurgical products, even if CooperSurgical has been advised, knew or should have known of the possibility of such damages. CooperSurgical's liability with respect to a product covered by a warranty or otherwise shall be limited in all circumstances to the purchase price of that product.

SECTION 16 – RETURNING PRODUCT FOR REPAIR

Please refer to the 'Troubleshooting' section in this manual before returning product. If you continue to have a problem with your device, please follow these instructions:

Returned Goods Policy

Goods will be accepted for return for the following reasons:

- If shipment was made without the customer's authorization or order
- If incorrect items were shipped
- If defective items were shipped
- If defective goods are covered by the standard warranty

To return product, please contact Customer Service for a Returned Merchandise Authorization (RMA) number. Items will not be accepted without an RMA number. Please have the following information:

- Reason you wish to return the goods
- Quantity, description, part number, serial number of the goods
- Date of receipt of order
- Customer's purchase order and the CooperSurgical invoice number

All used products will be cleaned and sterilized prior to shipment. A signed decontamination declaration may be required.

All products should be carefully and adequately packed, preferably in original packaging. Replacement items or additional repairs will be invoiced.

All packaging should be clearly labeled with the RMA number and statement "Urgent – Returned Items for Repair". If authorization to return a product is granted you will be provided with a return address label.

Shipments must be sent prepaid by the customer and insured for their full value during shipping. Freight collect shipments will not be accepted, and goods will be returned to the sender.

If the customer intends to return equipment ordered in error, the following restocking charges and terms will apply:

- 25 percent within 60 days from date of shipment
- Goods must be returned unused, in the original carton, and in marketable condition
- Refurbishing and replacement charges will be added to the restocking charges for damaged or missing items
- No return after 60 days
- No refund on sterile, single-use disposable products

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Customer Service Contact Details

Tel: +45 46 79 02 02

Fax: +45 46 79 03 02

E-mail: sales@coopersurgical.com

coopersurgical.com

Contact Details for Customers in the USA

Tel: 800-243-2974

Fax: 800-262-0105

coopersurgical.com

Obligation to Inform

Any serious incident that has occurred in relating to this device should be reported to CooperSurgical via phone number +1 203-601-5200 Ext 3100 or by email at ProductSurveillance@coopersurgical.com and to the local Health Authority in your country. A serious incident may have caused or contributed to a death, a delay in a procedure which resulted in death or serious injury, or a malfunction that could have caused an adverse event.