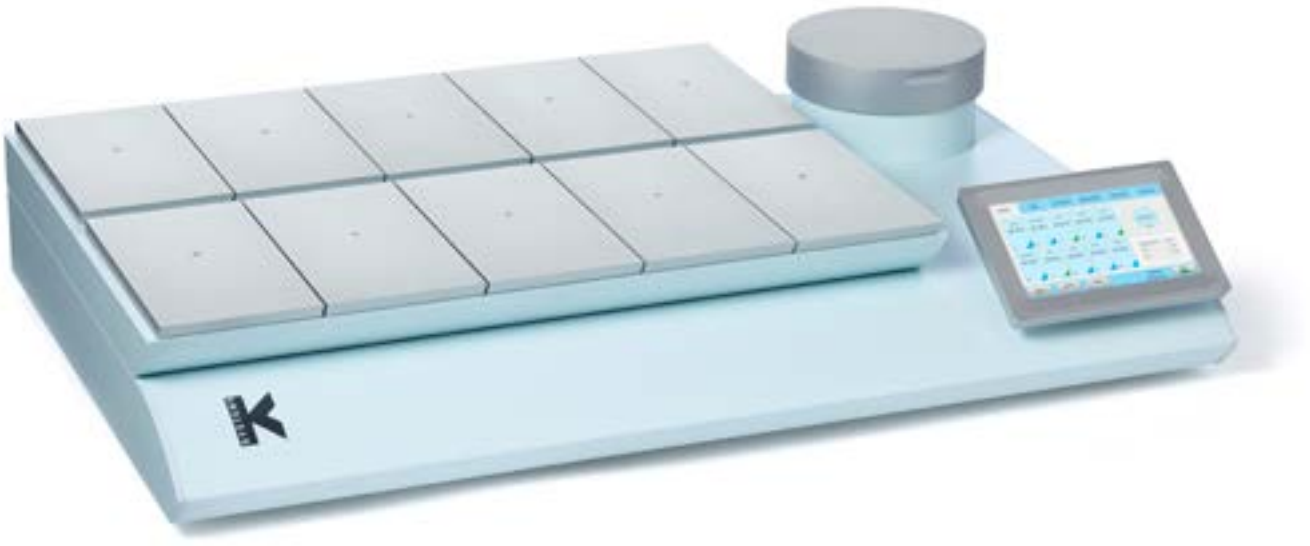
a CooperSurgical Fertility Company

User Manual

G210 InviCell

CO_2/O_2 Incubator



Models: InviCell Standard and InviCell Plus

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CE 0086

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Section 1 - Preface

Thank you for choosing a K-Systems product. We hope you will be happy with your G210 InviCell.

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 your embryos during long-term culture.

For optimal use of your 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 way you ensure having 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. The latest version of the User Manual can be downloaded from origio.com. This user manual belongs with the G210 InviCell incubator and should be passed on with the incubator if relocated to another facility.

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Section 2 - Safety

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

Cautions

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.

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.

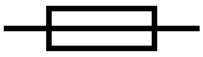
WARNING Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

CAUTION

- **DO NOT** use the incubator if ShockWatch or TipNTell has been triggered or if the package is damaged.
- Read and understand the manual completely before use. Keep the manual close to the unit.
- Never use or handle this unit in ways other than specified in this manual. Your safety may be at risk and the unit may get damaged.
- Never try to move the unit without consulting a person authorized by CooperSurgical.
- 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.
- 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.
- Make sure that CO_2 and N_2 gas supply pressures are maximum 1.0 bar and not below 0.5 bar.
- 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.
- Never use the unit without an original K-Systems K-730 filter.
- **DO NOT** expose the filter to liquids. Change filters that have been exposed to liquids.
- **DO NOT** leave lids open for more than 20 seconds.
- **DO NOT** use the unit at ambient temperatures exceeding 30°C. Ambient temperature above 30°C will compromise the incubation process. The relative humidity must not exceed 75% (non-condensing).

Symbols

Symbol	Meaning
	**WARNING:** Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
	**CAUTION:** Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.
	Consult the User Manual for information needed for proper use of the device.
	Manufacturer
	Date of manufacture
	Waste electrical and electronic equipment • CooperSurgical, and its distributors within the European Union and associated states, have taken the necessary steps to comply with the directive 2012/19/EU on waste electrical and electronic equipment (WEEE). • The instrument, when reaching its end of life, must be collected and recycled separately from other waste according to national requirements. Please contact your local CooperSurgical distributor for instructions. Environmental implications: WEEE contains materials that are potentially hazardous to the environment and to human health (see page 47).
	Serial Number
	Catalog Number

Symbol	Meaning
	This equipment must be protectively earthed
WARRANTY Void IF BROKEN	Warranty label
	Ethernet
Sample Port	Sample port
GAS (MAX 1 BAR)	Gas Inlets CO_2/N_2
	Static sensitive (ESD)
	Fuse
CE 0086	In accordance with Annex II of the European Medical Device Directive 93/42/EEC, as amended by Directive 2007/47/EC.
EC REP	Authorized Representative in the European Community

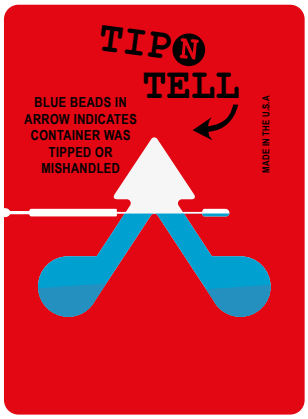
Section 3 - Installation

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 technical support.

Before Installation

This incubator is transported in a crate and we recommend you inspect its delivery. If the ShockWatch or TipNTell has been triggered, inform customer service.



Check the contents to ensure all parts listed on the packing list are present.

Placement

The G210 InviCell should be placed on a level, secure surface, away from heaters, coolers, air-conditioning outlets, mists, splash and direct sunlight. Allow 10cm of clearance on all sides to allow adequate ventilation.

Allow the G210 to acclimatize for two hours before installation.

To maintain a device setpoint between 35-40°C the preferred ambient temperature should be between 20-30°C. **DO NOT** use the incubator at ambient temperatures exceeding 30°C as this may compromise the incubation process.

This unit is designed for use at altitudes under 2,000 meters.

CAUTION

- Installation of the unit should only be performed by an authorized CooperSurgical Service Technician.
- Never block any of the ventilation holes on the unit.
- Make sure that all devices emitting electromagnetic radiation are kept at a reasonable distance from the unit in order to avoid any potential interferences.
- Make sure the power circuits used are intended for medical equipment.
- Make sure there is sufficient access to the device for ease of disconnection if required.

Section 4 - Intended Use

To provide an environment with controlled temperature at or near body temperature and gas level (CO_2, O_2 and N_2), for the development of human gametes and embryos during *in vitro* fertilization (IVF) treatment.

Applicable indications for use are subject to the regulations of the country into which the device is sold and also the availability of the G210 InviCell for clinical use is dependent on the regulatory approval status of the incubator within that country.

Applicable Part Numbers

Order Code	Description
K59500	InviCell Standard Incubator
K60000	InviCell Plus Incubator

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.

User Profile

A trained health professional, who has the appropriate assisted reproduction technologies qualifications. Only qualified personnel trained in using the G210 InviCell should operate the incubator.

> ⚠ **CAUTION:** If the equipment is used in a manner not specified by this manual, the safety of the user may be at risk and the equipment may be damaged. Always use the equipment as stated in this User Manual.

Operating Environment

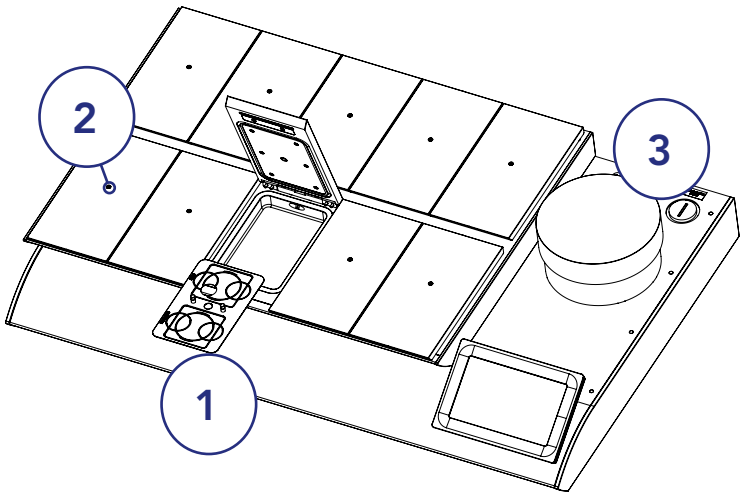
To be used at ambient temperature in a medical environment, clinic or hospital laboratory under normal working conditions.

Dish Inserts

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

4

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



Chamber Heating

Each chamber is heated with K-Systems unique non-inductive EM Neutra™ heating system, which provides a uniform heat distribution and ensures there is no electro-magnetic field around the embryos/gametes. All chambers have their own individual sensors to ensure stable temperatures at all times and unidirectional gas flow across the chambers ensures even gas distribution in each chamber.

Chamber Lid

Each lid has a sensor that, when opened, will disconnect the gas flow to minimize ambient air entering the chamber. 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 temperature sensor which will disconnect the gas flow when the lid is opened, to minimize the ingress of ambient air. The gas flow restarts immediately after closing the lid.

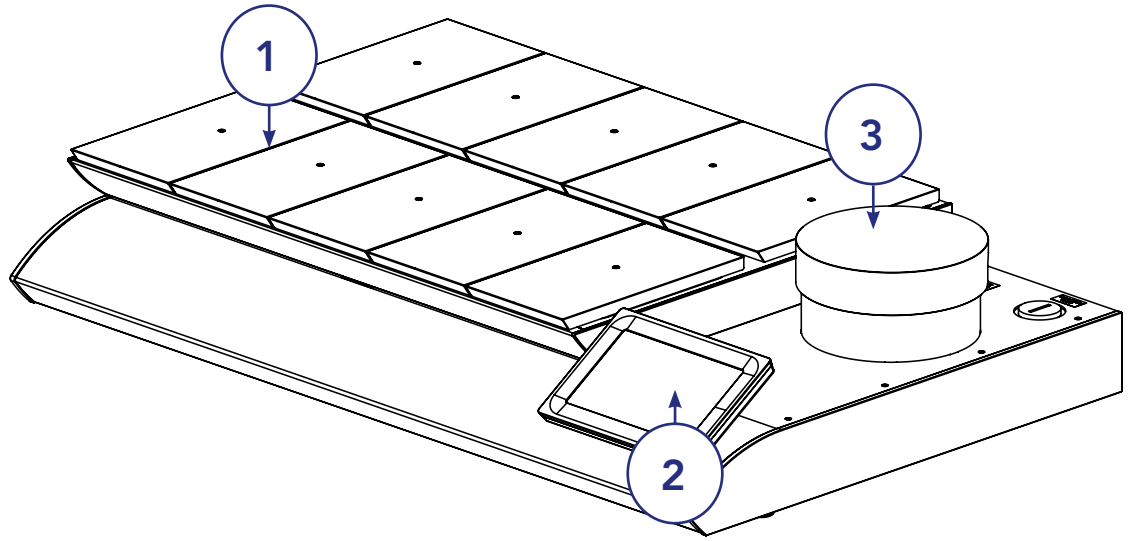
Gas flow to the Preparation Chamber can be disconnected by using the on/off button in system settings (see page 26).

Section 5 - Product Overview

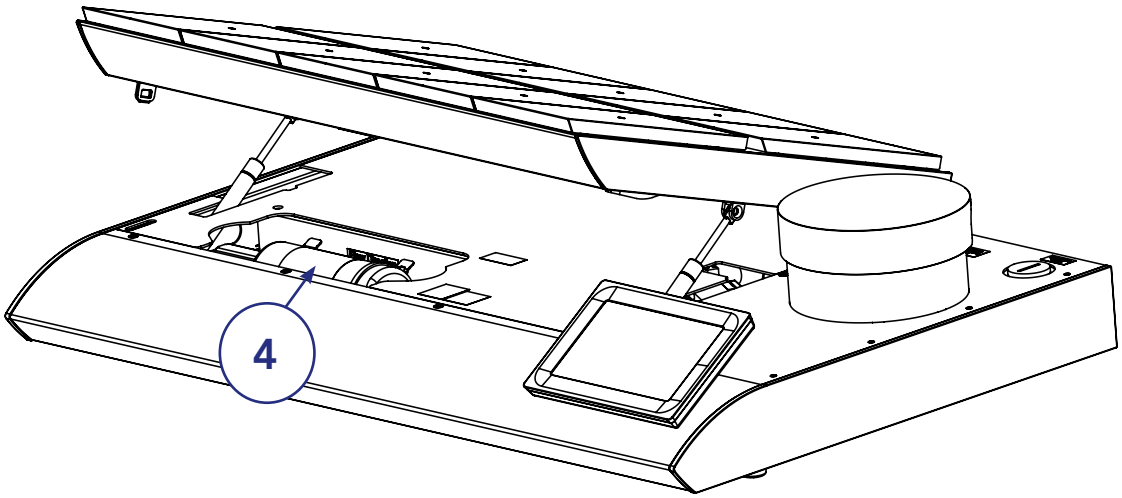
Main Components

	Components
1	Incubator Chambers
2	Touchscreen
3	Preparation Chamber
4	K-730 Filter

G210 InviCell Standard and Plus models - front view



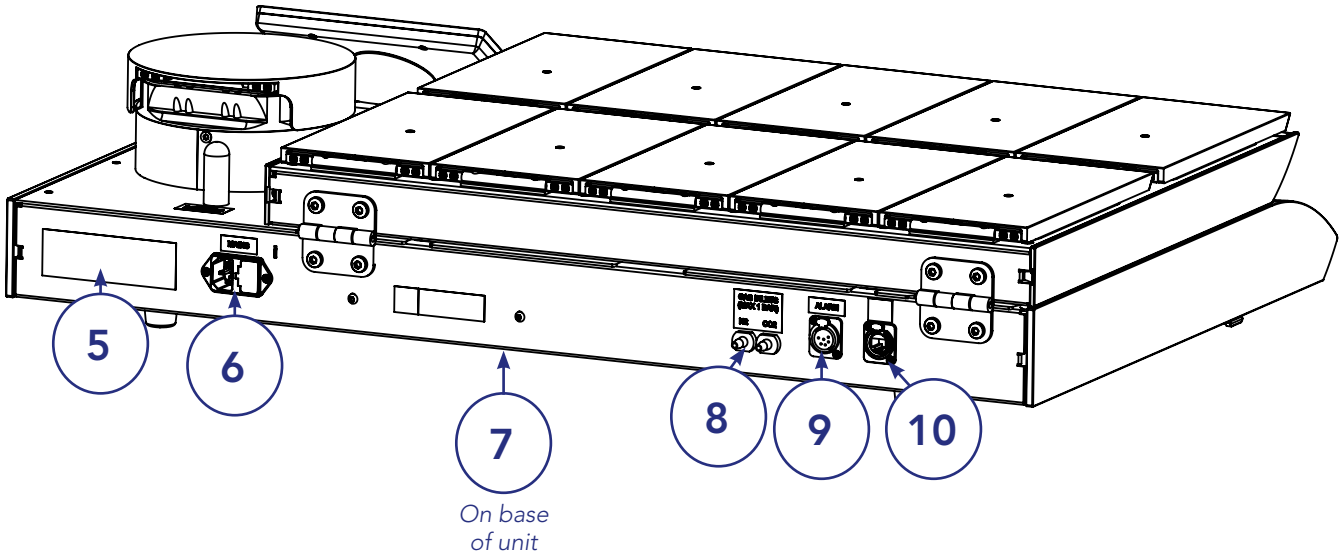
G210 InviCell Standard and Plus models - raised top section



	Components
5	Product label
6	Mains connection with fuse
7	Ventilation holes
8	Gas inlet connectors
9	Alarm output
10	Ethernet connector**

**External computing devices connected to the Ethernet on the unit must only be Limited Power Source and SELV circuit according to the standards IEC/UL 60950-1.

G210 InviCell Standard Model - back view
(see page 17 for InviCell Plus)



Supplied Accessories for G210 InviCell Standard

- 1 x K-730 Filter
- 2 x HEPA Inline Filter for input gas supply
- 10 Dish Inserts for Nunc®, Falcon® or Vitrolife®
- 2 x Silicone Tube Sealing Rings & Silicone Tube (3m)
- Gas sampling coupling
- 1 power cord
- 1 LAN cable (3m)
- 1 packet of Chamber Lid plugs (10 pieces)
- 1 USB drive containing K-Link software

Accessory Order Codes

Order Code	Description
23063-1	Falcon Dish Inserts 1 pc
23064-1	Nunc Dish Inserts 1 pc
22410-1	Nunc Dish Inserts 10 pc
23069	Vitrolife Dish Inserts 1 pc
23070-1	Vitrolife Dish Inserts 10 pc
22412-1	5 x Nunc Dish Inserts and 5 x Falcon Dish Inserts
23071-1	5 x Nunc Dish Inserts and 5 x Vitrolife Dish Inserts
23072-1	5 x Vitrolife Dish Inserts and 5 x Falcon Dish Inserts
23060-1	Dish Insert Nunc pH Online Sensor (Plus models only)
23061-1	Dish Insert Falcon pH Online Sensor (Plus models only)
23079	Dish Insert Vitrolife pH Online Sensor (Plus models only)
59556	K-730 Filter
53830	HEPA Inline Filter
59922	Lid Plugs, bag of 10
59901-1	Lid Seal for culture chambers
59902-1	Lid Seal for Preparation Chamber
59688	Gas sampler coupling
11103	G100 Gas Analyzer
11006	Solid Temperature Sensor (use with K-Systems F100 Thermometer)
59655	XLR6 Receptacle Connector
32903	User Manual
60017	Connector for External CO_2 sensor MTG (Plus models only)
60014	Connector for External CO_2 sensor Vaisala (Plus models only)
60018	25 Pin D-Sub male connector prepared for soldering (Plus models only)
60019	24VDC power supply (Plus models only)

Specification Table

Criteria	Specification
Overall dimensions, (L x W x H)	860mm x 550mm x 180mm
Weight	53kg maximum
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, CO_2 gas, N_2 gas, Sampler port, Ethernet, Alarm
Alarms	Visual and audible alarm for out of range temperature and gas
Filter (HEPA/ VOC)	K-730 Filter
IP class	IP30
Overvoltage category	Transient overvoltage II
Pollution degree rating for electrical equipment	2
Power specifications 100 – 240 VAC	
Max consumption	270W
Voltage	1/N/PE AC, 100 - 240VAC Class 1 type B
Frequency	50/60 Hz
Current	3.2A
Mains supply voltage fluctuations	Up to +/-10 % of the nominal voltage
Fuses 100 - 240V UL Listed	
Mains connection	T2.7AL
Ambient conditions	
Working temperature and humidity	20 – 30°C. Less than 75% RH (non-condensing)
Transport and storage temperature and humidity	5 – 50°C. Less than 95% RH (non-condensing) Maximum one week at 50°C

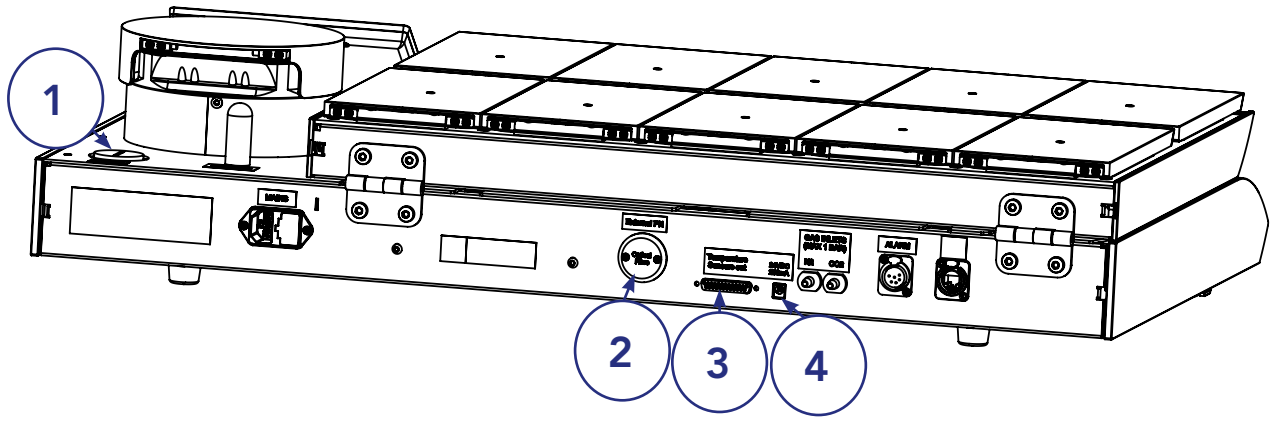
Section 6 - G210 InviCell Plus

G210 InviCell Plus supports external and independent movement and monitoring of the most critical parameters regarding the performance of culture media, CO_2 concentration, temperature and pH measurement.

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

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

G210 InviCell Plus - back view



	Component
1	Connection for external CO_2 sensor
2	Connection for external pH monitoring (pH Online™)
3	Data connection for external thermometer and power
4	Power connection for external thermometer and power

External Sensors, pH / CO_2

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

- External pH: OCTAX Log & Guard™ from MTG GmbH
- External CO_2: OCTAX Log & Guard™ CO_2 sensor from MTG
  GMP251 Carbon Dioxide Probe from Vaisala Oyj

These parts need to be purchased separately, directly from MTG GmbH or Vaisala Oyj.

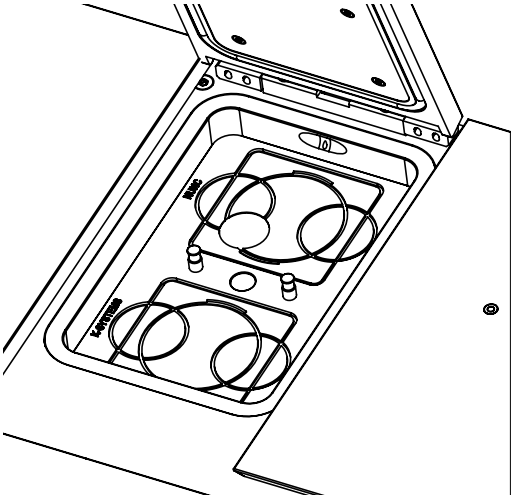
An external CO_2 connector for the GMP251 Carbon Dioxide Probe from Vaisala Oyj is enclosed. Connectors can to be ordered separately.

- OCTAX Log & Guard™ CO_2 sensor from MTG
- GMP251 Carbon Dioxide Probe from Vaisala Oyj

Dish Insert for pH Online

A special Dish Insert must be used in the chamber were the pH optical fibre sensor is installed. There are three different Dish Inserts available depending on the dishes used:

- Dish Insert Nunc pH Online Sensor: Order code: 23060-1
- Dish Insert Falcon pH Online Sensor: Order code: 23061-1
- Dish Insert Vitrolife pH Online Sensor: Order code: 23079



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External Temperature

You will need:

- 25 Pin D-Sub male connector prepared for soldering
- 24 VDC power supply

Further information is available in the Installation Guide for the G210 InviCell Plus.

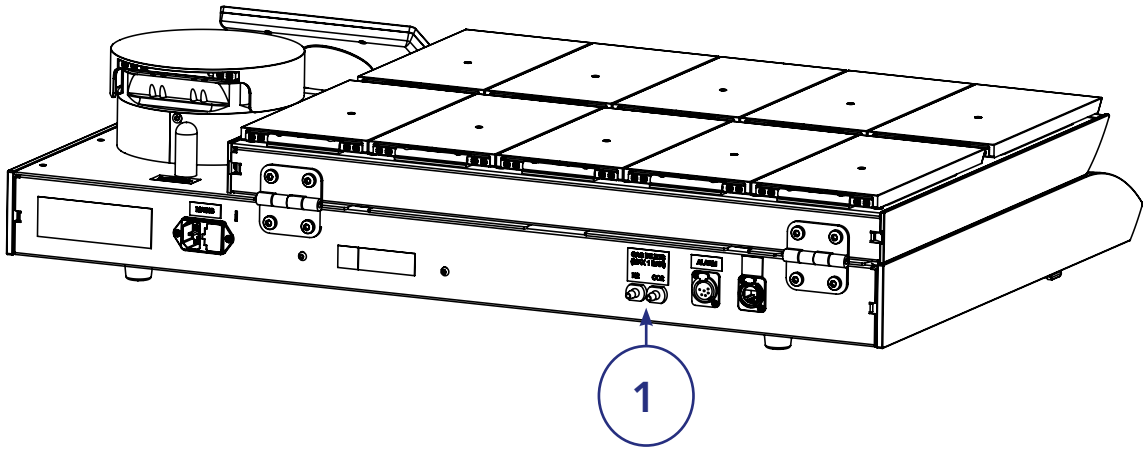
Additionally Supplied Accessories for G210 InviCell Plus

- Connector for GMP251 Carbon Dioxide Probe from Vaisala Oyj
- 25 Pin D-Sub male connector prepared for soldering
- 24 VDC power supply

Section 7 - Set-up

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

Gas Supply



1. The G210 is not supplied sterile and should be cleaned before use. Make sure the gas input and output ports at the back of the incubator are also cleaned. See “Section 12 - Maintenance” on page 40.
2. Install the K-730 filter, see “Replacing the K-730 Filter” on page 46.
3. Connect the gas supply via the gas connectors (1) at the back of the unit.
4. Turn on incubator.
5. Make sure the incubation temperature, gas mixture etc, settings are as desired using the Settings Menu on the touchscreen. After 30 minutes the unit will be at a constant working temperature and air flow (see “Changing the Temperature Setpoint” on page 24).
6. Set correct date and time before connecting to the network (LAN).

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 is supplied with the following factory settings

Criteria	Setting
Temperature	37.0° C
Gas concentration	CO_2: 5.0% O_2: 5.0 %
Gas flow*	CO_2: 1.5 l/h* N_2:7 l/h*

*When G210 is stable and CO_2 and O_2 gas concentration setpoints are 5.0%

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 (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 12).

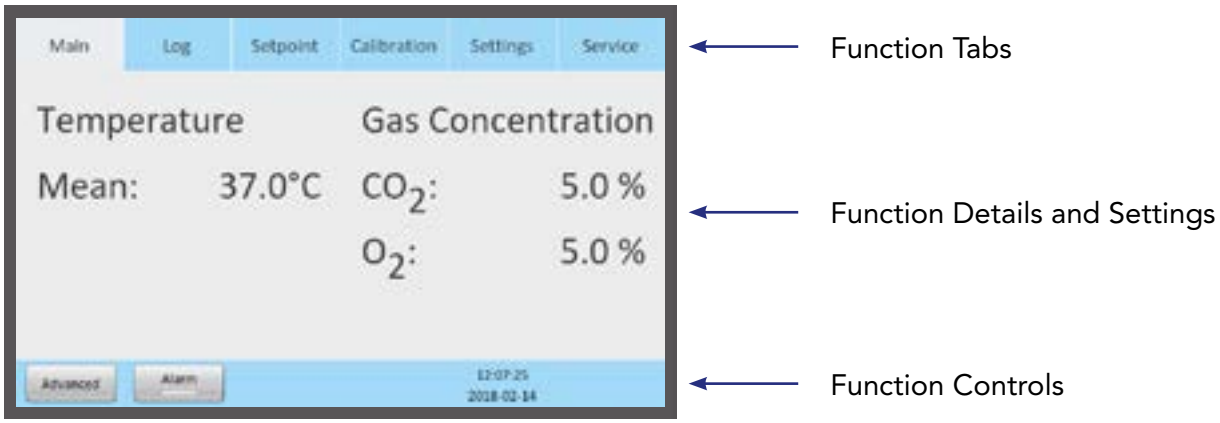
1. Place the Dish Inserts in the chamber and close the lid.
2. Wait 30 minutes for the Dish Inserts to heat up.
3. Open the chamber lid.
4. Place the culture dishes containing gametes or embryos on the Dish Inserts ensuring they are placed securely in the correct milled grooves.
5. Close the lid.
6. Enter the patient ID as per "Edit Chamber Information" on page 22.

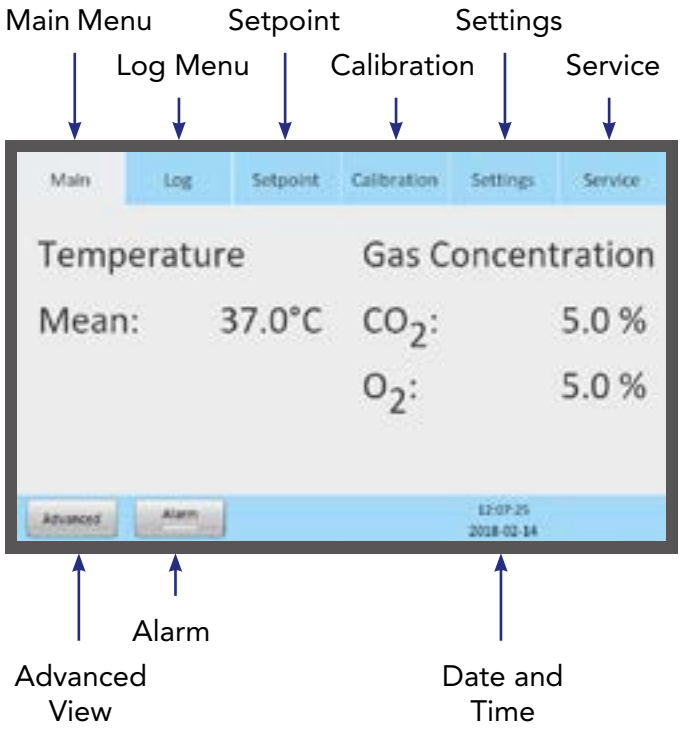
Touchscreen Menu

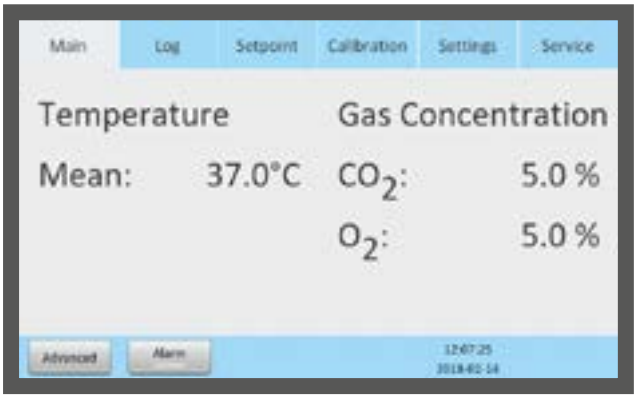
All the unit's functions and settings are controlled from the touchscreen.

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

The touchscreen can be operated with gloves.



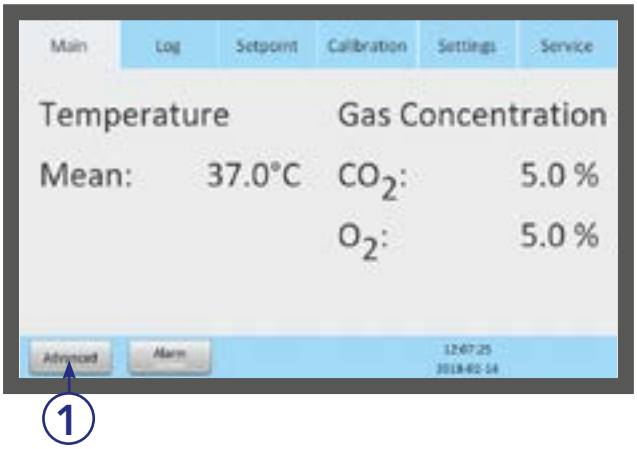




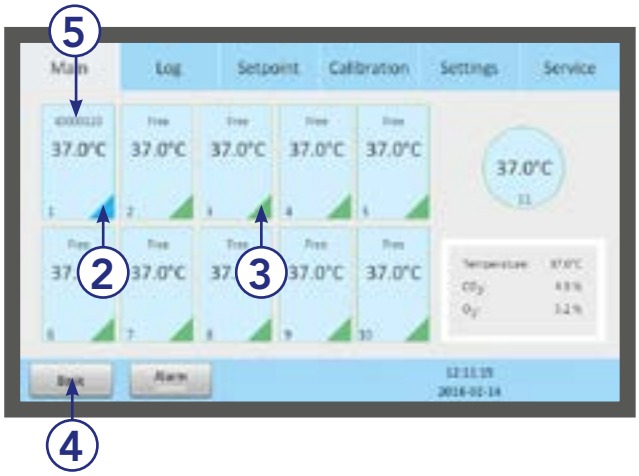
Main Menu

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).

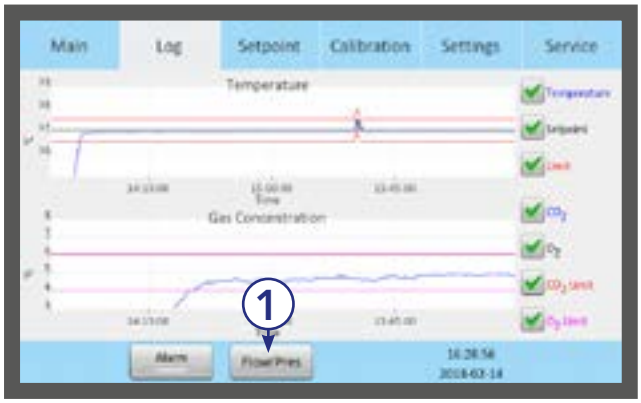
Chamber Information

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 you press a text field, 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).

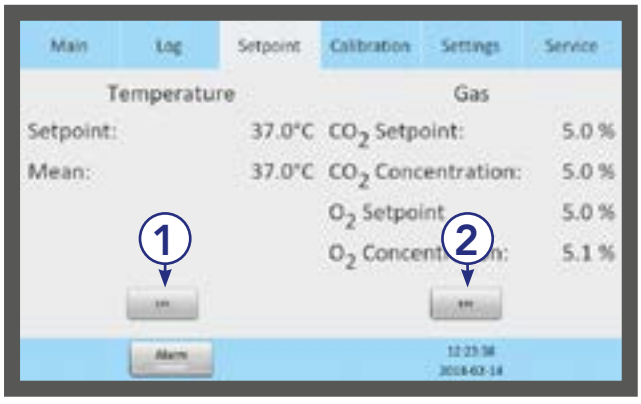
4. Press Next (5) to continue to the next step, if required.



Log

1. The Log tab 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.

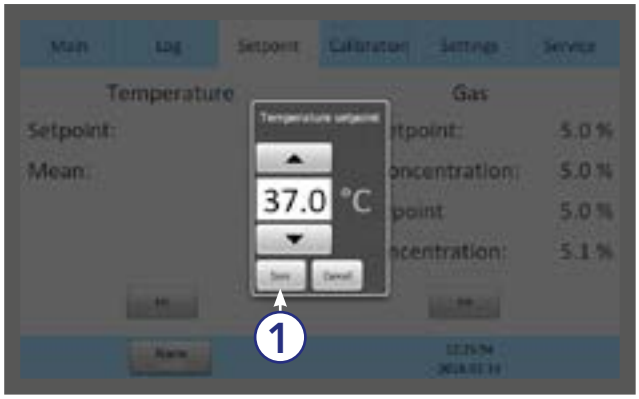


Setpoint

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

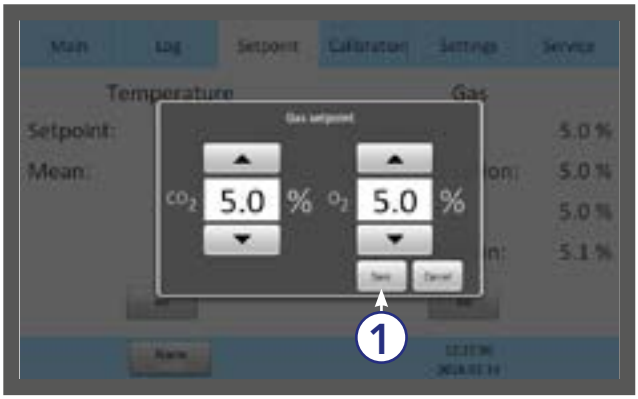
2. Only administrators and advanced users have access to change the setpoints. Select a user and press OK (3) .

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



Changing the Temperature Setpoint

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

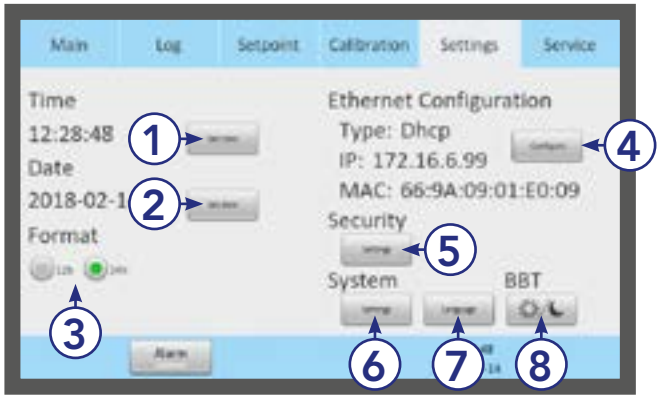


Changing the Gas Setpoint

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:

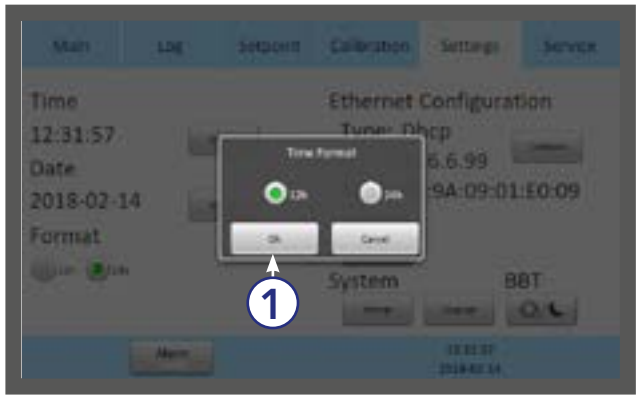
1. Time settings (1)
2. Date settings (2)
3. Time format (3)
4. Ethernet configuration (4)
5. Security settings (5)
6. System settings (6)
7. Language (7)
8. Basal Body Temperature (BBT) settings (8)

To change some of these settings requires a login (see "Security Settings" on page 27 and "Access Levels" on page 28).

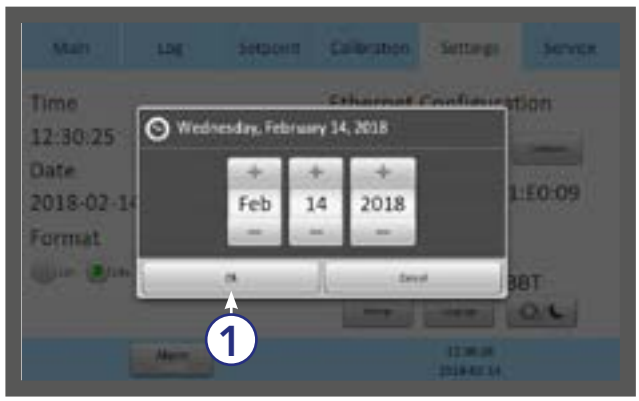
Changing the Date and Time

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. We recommend allocating a static IP address to the device. However, you will need to consult with your IT department for network settings.

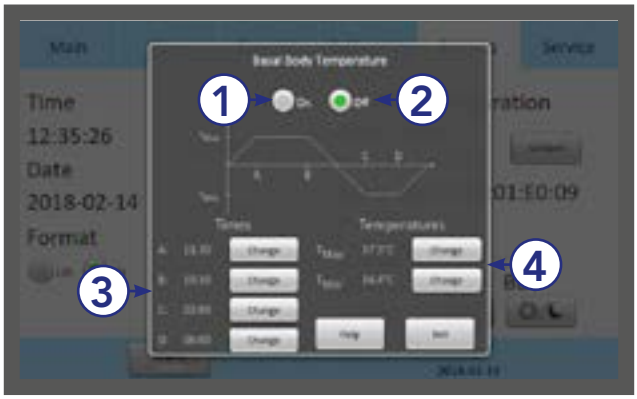
1. Select DHCP (1), or
2. Static IP (2)
3. If static IP is selected, enter the settings provided by your IT department.
4. Press Save (3).

Changing the Preparation Chamber Settings

Select the Systems button from the settings menu. Changing UV light, CO_2 regulator, O_2 regulator and gas supply to the Preparation Chamber on or off.

Changing Language

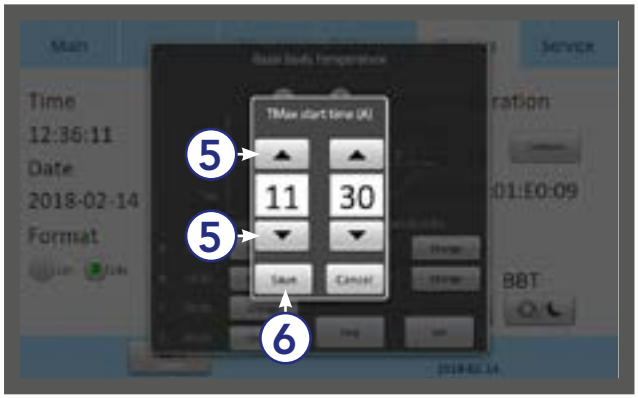
Select the Language button from the settings menu. Choose your preferred language in the language menu.



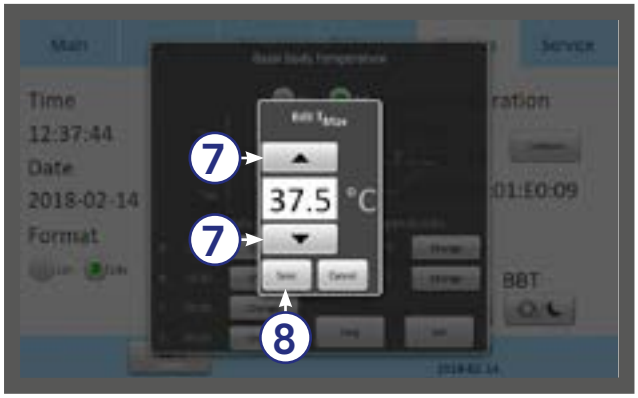
Changing Basal Body Temperature

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 you can create new users and assign their 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 authorization, 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.

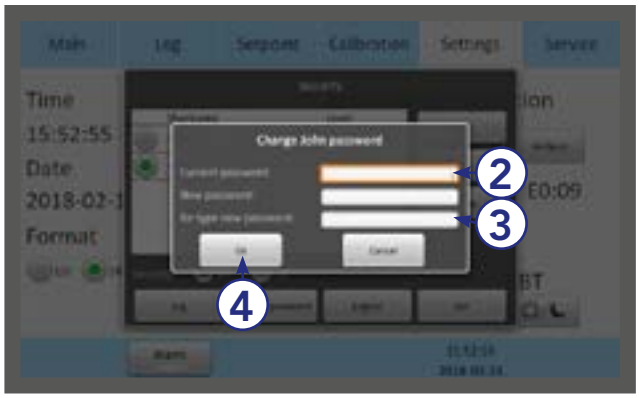
Edit User

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

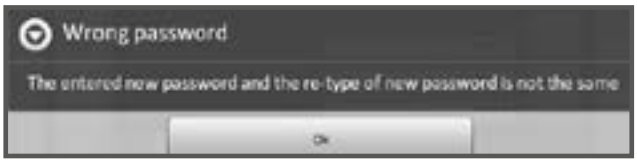
2. The access level, name and password can be edited here. Press Save (2) when done.

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 your 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.

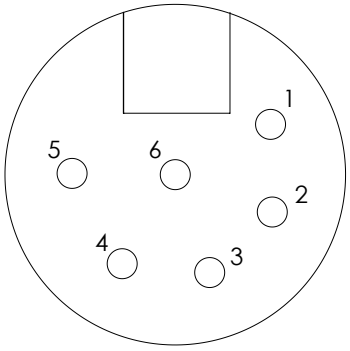
The alarm will be activated:

- If the chamber temperature is too high or too low.
- If the gas concentrations are too high or too low.
- When there is a UV-Lamp error.
- 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.

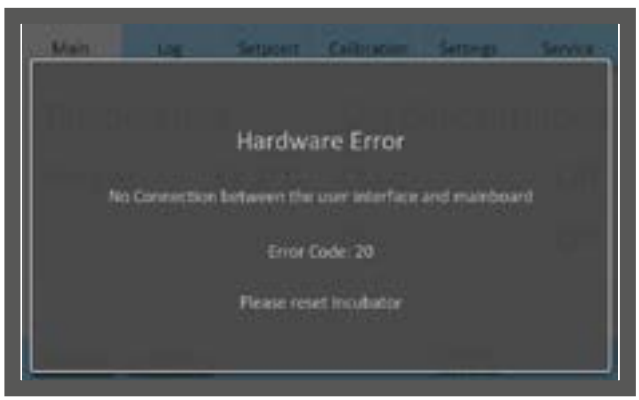
External Alarm Connector

This section for installers of third-party monitoring systems



XLR6 Receptacle Connector:

- Alarm 1: Position 1-2 responds to Gas alarm
- Alarm 2: Position 3-4 responds to Pressure alarm
- Alarm 3: Position 5-6 responds to Temperature alarm
- Alarm output: Rated to max 24V/1A



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 38.

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

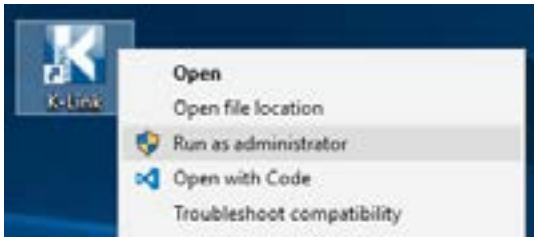
K-Link software can be used to communicate with a G210 over a TCP/IP network to retrieve, display and save a log of measurements, warnings, and daily averages into a spreadsheet. K-Link can also be configured to send email notifications when alarms are triggered.

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". You may be prompted to enter alternative credentials. Consult your IT Department for further details.

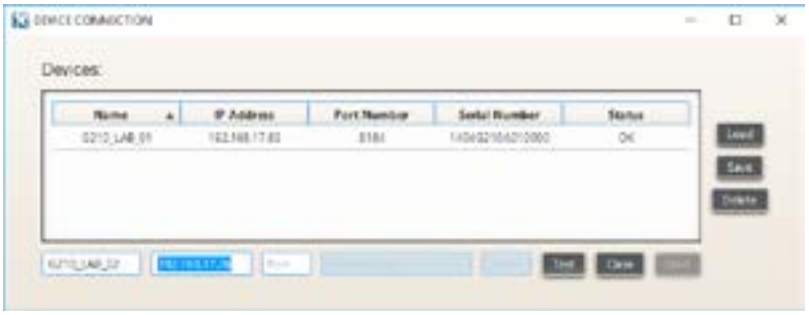


The K-Link loading screen is displayed for a few seconds while the software loads.

Device Connection

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

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".

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

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

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

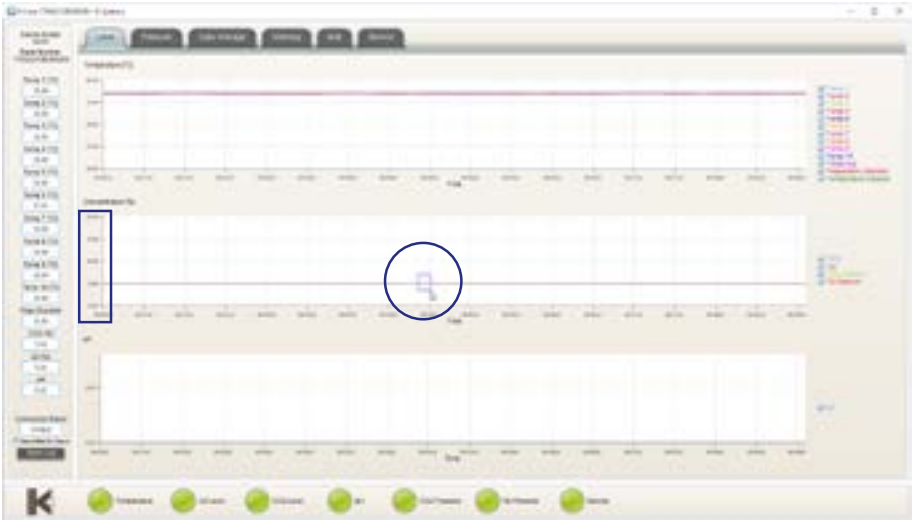
The measurement section displays the measurements retrieved from the device every 30 seconds, the connection status of the device, a setting to enable or disable email notifications if an alarm is triggered, and an "Open Log" button to explore the folder containing the file where the logs are being saved.

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.

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.



Level Tab

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

Pressure Tab

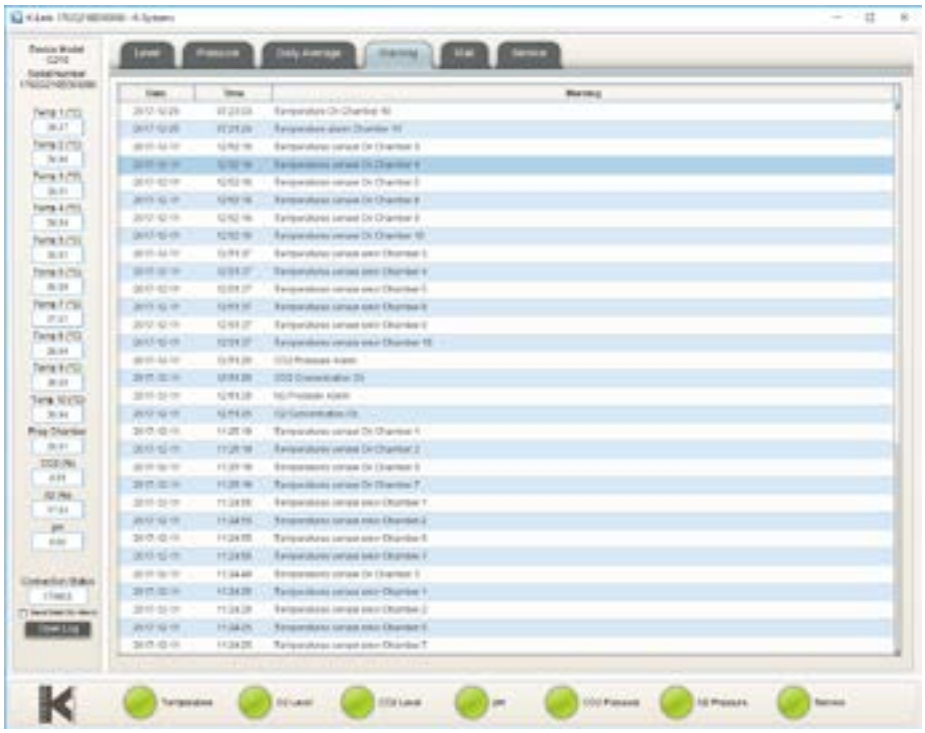
The Pressure tab displays a graph of the device measurements over time.

Daily Average Tab

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

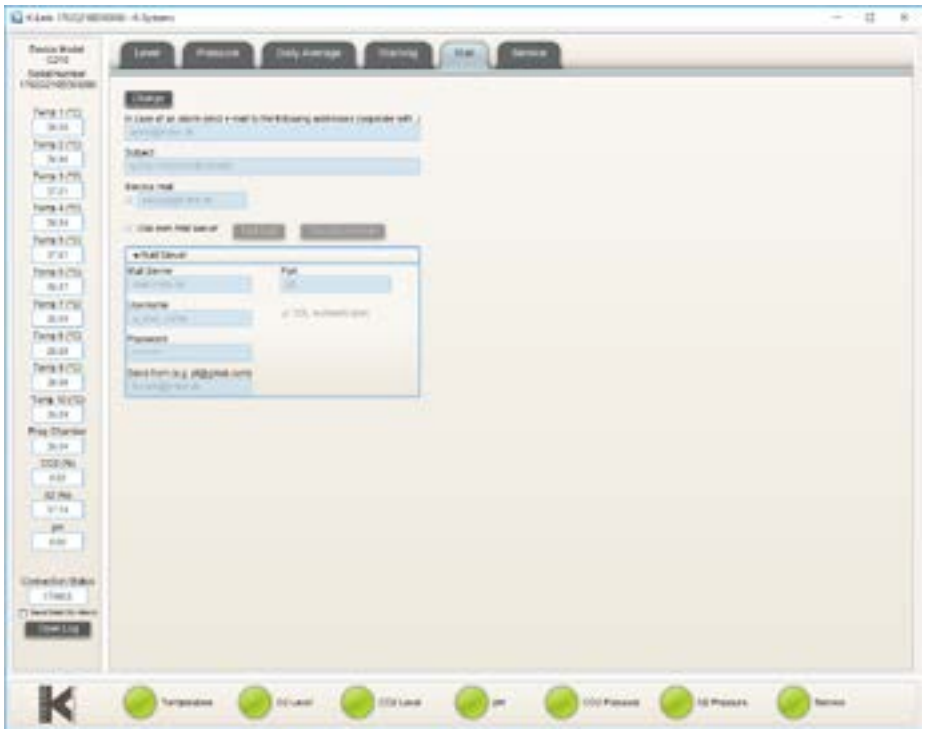
Warning Tab

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



Mail Tab

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



NOTE: It is recommended to configure K-Link to use your own mail server. Consult your IT Department for your 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 or a UV light 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.

Section 11 - Troubleshooting

Heating System

Symptom	Cause	Action
Wrong temperature	The alarm is on	The temperature is more than 0.5°C off from the setpoint, 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 desired temperature setpoint
Temperature differs between chambers	System not properly calibrated	Calibrate each zone according to the User Manual using a high precision thermometer (see page 44)

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
	Actual gas concentration is higher or lower than setpoint	Calibration of the gas concentration is needed.
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
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	The coupling is connected to the sample port	Remove the coupling and replace the protection cap (see page 42)
	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 is emptied of gas	Turn off G210. Restart the G210. Let gasses stabilize
Wrong gas concentration in one chamber	Lid plug has been penetrated more the 5 times	Replace lid plug

Touchscreen

Symptom	Cause	Action
Absent or erratic function of operation buttons	Failure in the touchscreen	Replace touchscreen. Contact your service representative
Missing pixel in touchscreen	Failure in the LED screen	Replace touchscreen. Contact your service representative
Repeat closure and opening of Android screen	Inconsistency between the date and time on Android and PC	Synchronize date and time on G210 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, 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.

Periodic Cleaning

The G210 InviCell should be cleaned with sterile water.

1. Moisten a sterile cloth with sterile water and wipe all internal and external surfaces of the chambers including lids.
2. Leave the lids open and allow to dry completely before use.
3. Close the lids and start the unit and let it run for a minimum of 30 minutes (with or without gas).
4. Complete validation check.

Disinfection

Disinfect the G210 InviCell in cases of contamination and/or spillage. Cleaning should precede disinfection.

1. Promptly soak up excess liquid using a sterile cloth.
2. Wipe all internal surfaces of chambers and lids with sterile wipes moistened with a disinfection solution containing 0.12% of active chlorine.
3. Leave for 15 minutes. (The solution will be active even when it is dry.)
4. Moisten a sterile cloth with purified or sterile water and wipe all disinfected surfaces.
5. Leave the lids open and allow to dry completely before use.
6. Close the lids and start the unit, and let it run for a minimum of 30 minutes (with or without gas).
7. Complete validation check.

Sterilizing the Dish Inserts

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

1. Promptly soak up excess liquid using a sterile cloth.
2. Remove the Dish Insert from the chamber.
3. Moisten a sterile cloth with sterile water and wipe all surfaces, especially all the milled grooves.
4. Wrap Dish Inserts in steam permeable plastic film or paper and place in autoclave.
5. Autoclave for 20 min at 121°C at 2 bar (29 psi).
6. Remove and allow to cool completely before use (minimum 30 minutes).

7. Complete validation check.

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 is not emptied of gas during the calibration procedure. To do so will cause very 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 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)
2. Via the silicone plug on each of the chamber lids

DO NOT collect more than 0.1l of gas from either mixing chamber or chambers.

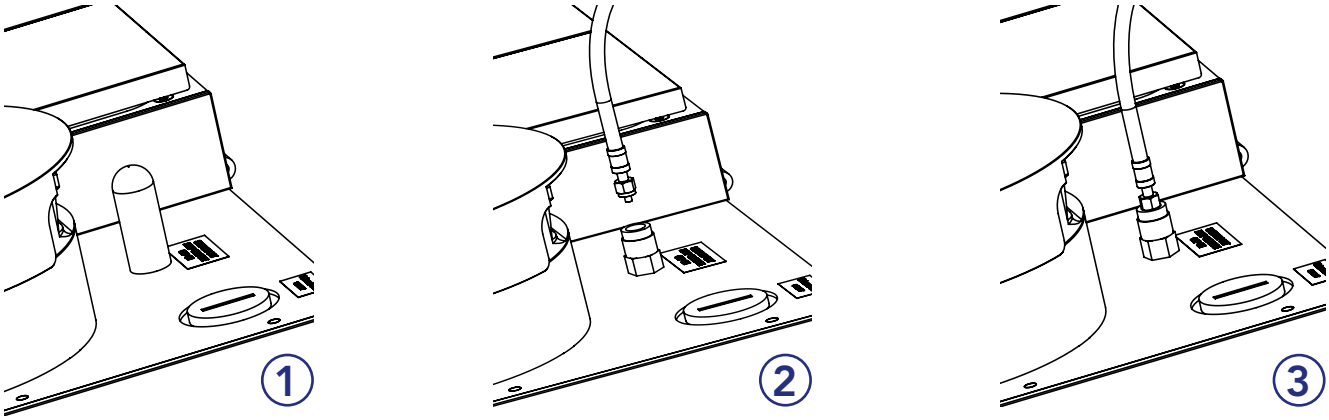
Always check the gas concentration in the setpoint menu during sampling. If the gas concentration differs more than 0.1% from the setpoint, allow the G210 to stabilize to the gas concentration set point before taking the next gas sample.

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) which recirculates gas into the gas flow during sampling. If not using a recirculating gas analyzer, allow the incubator to stabilize for 3 minutes after each sample collection. Ensure the gas analyzer is prepared as per the gas analyzer user manual.

Gas flow to the Preparation Chamber should be disconnected during gas calibration (see page 26 Changing the Preparation Chamber Settings).

Gas Sample Port

The Gas Sample Port is located behind the Preparation Chamber. The Gas Sample Port is connected directly to the gas-mixing chamber.



1. Connect a short length of tubing to the gas analyzer input.
2. Connect the enclosed coupling to the other end of the tubing.
3. Remove the protection cap from the sample port.
4. Connect the coupling to the incubator sample port.
5. Connect a short length of tubing to the gas analyzer output.
6. Connect the other end into the lid plug of chamber 8, using a 25 - gauge needle. This re-circulates gas back into the incubator.

   To obtain a faster stable reading from the sample port, or chamber lid plug, purge the gas anaylzer of gases by

   - Running the pump (no more than) 30 seconds
   - Stopping the pump for 30 - 40 seconds to allow the gas to stabilize
7. Collect the gas sample.
8. Run the pump for (no more than) 50 seconds.
9. Stop the pump.
10. Record the gas concentration reading.
11. Disconnect the coupling from the sample port.
12. Replace the protection cap.

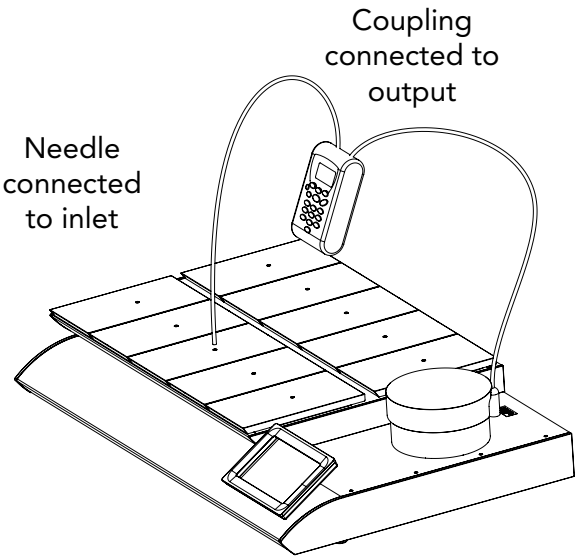
If calibration is needed, adjust the value on the calibration, wait for the gas to stabilize and re-test (no need to purge gas analyzer if already connected).

Gas flow to the Preparation Chamber should be switched back on (see page 26 Changing the Preparation Settings).

12 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 outlet. Do not use needles larger than 0.5 mm x 25 mm. 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.

By following this protocol, the sampled gas re-enters the gas flow as subsequent samples are collected from the next chamber. If gas is not circulated, wait 3 minutes between sampling.



Verification of Gas Concentration in Chambers

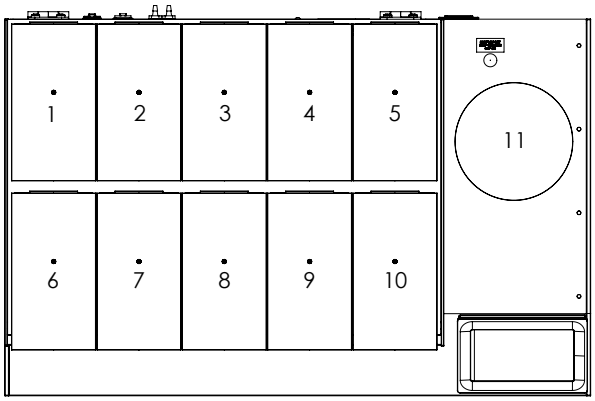
1. Connect a short length of tubing to the gas analyzer input.
2. Connect the other end of the tubing to the lid plug of chamber 8 using a 25-gauge needle.
3. Connect a short length of tubing to the gas analyzer output.
4. Remove the protection cap from the sample port.
5. Connect the enclosed coupling to the other end of tubing.
6. Connect the coupling to the incubator sample port to re-circulate gas back to incubator.

   To obtain a faster stable reading either from sample port or lid plug, follow the procedure below to purge outside air from gas analyzer:

   - Run the pump (no more than) 30 seconds
   - Stop the pump for 30-40 seconds to allow the gas to stabilize.
7. Run the pump for (no more than) 50 seconds. Stop the pump and record gas concentration reading.

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



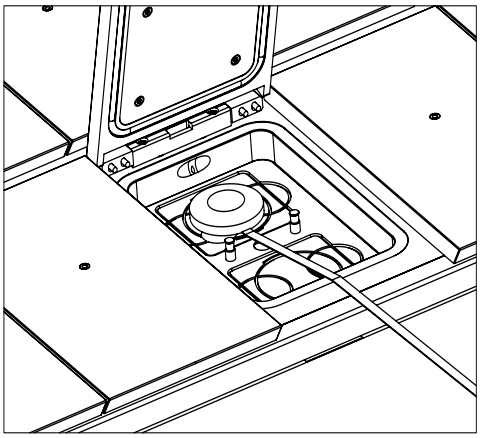
8. Move the needle swiftly to chamber and repeat.
9. Take the average value of the O_2 concentrations in the chamber with the highest and lowest O_2 concentration and change your calibration setpoint according to this value.
10. Adjust the CO_2 calibration setpoint if necessary, according to instructions on page 24).
11. If a chamber is more than +/- 0.5 from gas setpoint, please contact your local Service Technician.
12. Dissasemble the coupling from the sample port and replace the protection cap.

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.

We recommend 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.
5. Adjust the calibration setpoint by pressing the icon representing the requested chamber. See “Changing the Temperature Setpoint” on page 24.
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 24.
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.

NOTE: Use only recommended thermometer and temperature probe equipment.

Alarm Function Test

The temperature alarm is tested by setting the temperature setpoint to, for instance, 36°C, and then manually turning down the temperature to a lower value. See “Alarm” on page 31. The alarm should be heard within a few minutes.

Section 13 - Service

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

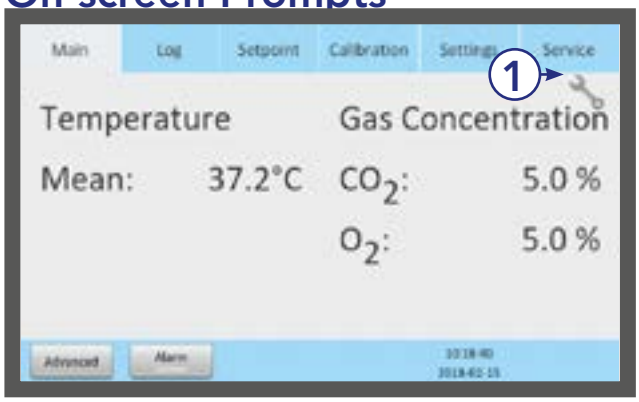
For the reliable and safe operation of this incubator it is strongly recommended that inspections and services are performed as stated in the Service Plan below. Failing to follow this plan may cause the unit to stop performing as intended and cause damage to embryos, blastocysts etc kept inside the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

Service Plan

Conducted by	User	Authorised Service Representative		
Component name	Every 3 months	Every year	Every 3 years	Every 6 years
Replace K-730 Filter Capsule	X			
Replace UV light bulb		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

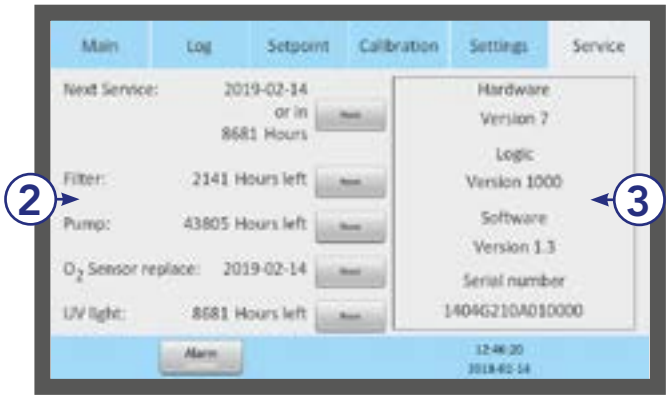
*Gas calibration should be performed after replacing O_2 and CO_2 sensors.

On-screen Prompts



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

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

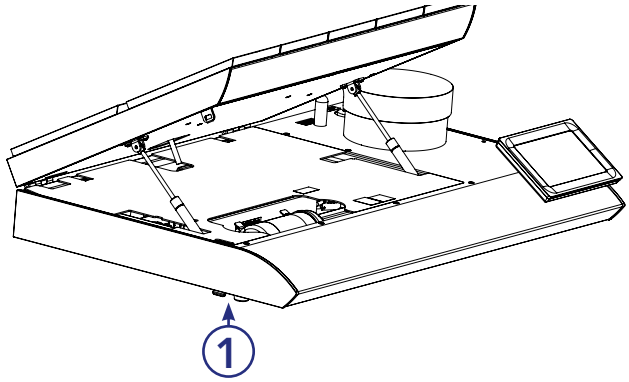


This screen (3) also displays hardware and software versions currently installed and the unit's serial number.

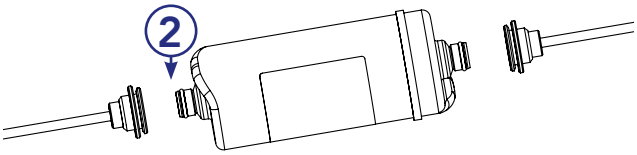
Replacing the K-730 Filter

Remove all samples from the chambers before replacing the filters.

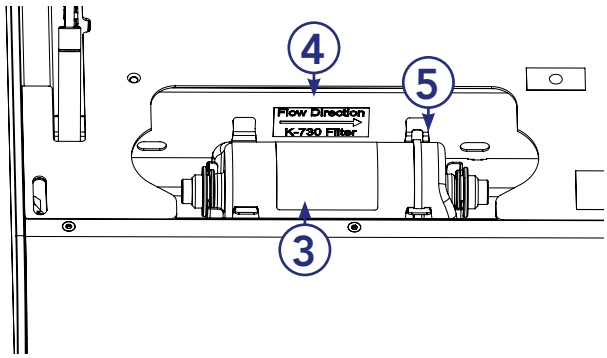
1. To access to the filter compartment, push the safety lock lever (1) and lift the upper part of the incubator containing the chambers.



2. Fasten the connectors to the inlet and outlet of the K-730 Filter (2).



3. Ensure the direction of flow shown on the K-730 Filter label (3) is consistent with the flow direction (4) shown inside the filter compartment.
4. Place the K-730 Filter in the filter holder with the label facing up (5).
5. Lower the upper part of the incubator.



CAUTION: Do not use the unit without a genuine K-Systems K-730 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 K-730 Filter

CAUTION: Contamination Hazard

As the filter may have been used for processing and treating infectious substances, it might be contaminated. The used K-730 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 (including light source) must be disinfected.

Environmental Protection for Disposal of the Product

The unit contains reusable materials. All components (with the exception of the K-730 Filter) can be discarded as electrical waste after cleaning and disinfection.

Please note that K-730 Filters must be discarded in accordance with the applicable national regulations for special solid waste.

If any electronic component is no longer serviceable, it must be sent back to CooperSurgical to be destroyed in an environmentally safe way. 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	Aluminum
Exterior housing	Mild Steel, Aluminum, Stainless Steel
Interior housing	Aluminum and POM
Printed circuit board	Enclosed electronic components mounted on a PCB

Section 15 - Warranty Information and Limits on Liability

15

CooperSurgical warrants that this item will be free from defects in materials and workmanship for one year from the date of initial purchase.

If CooperSurgical determines that the product fails to conform to that warranty during the one-year warranty period, CooperSurgical will, as the sole remedy for that failure to conform, 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. A customer will not have any remedy if the product does not conform to the warranty for that product unless that product is returned to CooperSurgical in accordance with that Returned Goods Policy. CooperSurgical will ship returned products that it repaired or replaced under warranty to the customer who returned those products, at CooperSurgical's expense F.O.B. the customer's facility. Under all other circumstances, CooperSurgical will ship returned products to the customer who returned those products at the customer's expense F.O.B. CooperSurgical's facility.

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 limited-use, 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.

The above warranties are in lieu of, and CooperSurgical hereby disclaims, all other warranties, express or implied, written or oral, with respect to CooperSurgical's 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's 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.

Returned Goods Policy

1. 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

2. To return goods, contact Technical Support for a Returned Merchandise Authorization (RMA) number. Items will not be accepted without an RMA number. Please have the following information:
   - Reason for returning the goods
   - Quantity, description, part number, serial number of the goods
   - Date of receipt of order
   - Customer's purchase order and the (CooperSurgical or ORIGIO) invoice number

   All used goods must be decontaminated prior to shipment. A signed decontamination declaration may be required.
3. Shipment must be sent prepaid by the customer. Freight collect shipments will not be accepted, and goods will be returned to sender.
4. 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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