

EmbryoScope™ time-lapse incubator

User manual



Caution: Federal law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.

EmbryoScope time-lapse incubator, model D, software version 7.9

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1 Introduction

This user manual provides information on how to use the EmbryoScope time-lapse incubator Version D (hereafter EmbryoScope time-lapse incubator).

A person certified by Vitrolife will perform scheduled maintenance and recalibration checks according to a service plan to ensure continued safe and efficient operation. The end user is strongly encouraged to follow the service plan carefully to ensure error-free operation of the equipment.

The EmbryoScope time-lapse incubator is a medical device that must be operated by trained personnel according to the instructions contained in this user manual. Users must be qualified to operate the device and qualified to perform procedures associated with device use in accordance with local qualification standards.

The product fulfills the requirements of the UL 60601-1 edition 1 and IEC 60601-1:2005 + corr. 1 (2006) + corr. 2 (2007) standards; class I, type B equivalent. The EmbryoScope time-lapse incubator is suitable for continuous operation.

- The EmbryoScope time-lapse incubator and related accessories conform to the requirements of Regulation (EU) 2017/745 on medical devices, classified as class IIa.
- Conforms to ANSI/AAMI ES 60601-1:2005 + A1 + A2.
- Certified to CAN/CSA - C22.2 No. 60601-1:R2013 addendum.

1.1 Warnings, restrictions and limited warranty

Users must agree to read and understand this user manual and observe the safety instructions before operating the EmbryoScope time-lapse incubator.

RESTRICTIONS ON USE
<ul style="list-style-type: none">• The EmbryoScope time-lapse incubator may only be used by persons who have been trained in its use by a person certified by Vitrolife.• The EmbryoScope time-lapse incubator may only be used with sterile disposable EmbryoSlide culture dishes produced and sold by Vitrolife.• The EmbryoSlide culture dishes may not be reused.• The EmbryoSlide culture dishes must be covered with sterile lids before insertion into the EmbryoScope time-lapse incubator.• The EmbryoScope time-lapse incubator may not be used in a wet environment. No fluids other than culture medium and oil and the cleaning agents specified in this user manual may be used in or near the incubator.• Never cover the vent holes on the back of the incubator in part or in whole as this may cause the incubator to overheat.• Users should contact Vitrolife immediately to report any incident and/or injury to a patient, operator or maintenance employee that occurred as a result of operating the EmbryoScope time-lapse incubator. Any serious incident that has occurred in relation to the incubator should be reported to the competent authority of the Member State in which the user is established.• Should an accident occur while using the EmbryoScope time-lapse incubator, stop using the time-lapse incubator until it has been checked by a person certified by Vitrolife.

WARNING

- The EmbryoScope time-lapse incubator includes moving parts with safety stops. Do not try to block safety sensors by inserting a finger or a hand into the EmbryoScope time-lapse incubator while it is turned on. This is dangerous and may cause injury.
- To avoid risk of electric shock, this equipment must only be connected to a mains supply with a protective earth, which is connected to a residual-current device (RCD) or ground fault (circuit) interrupter (GFI/GFCI).
- The EmbryoScope time-lapse incubator should always be connected to a local uninterruptible power supply (UPS) to ensure stable operating conditions in case of power failure.
- Portable and mobile RF communications equipment may affect the EmbryoScope time-lapse incubator.
- Mishandling or misuse of the EmbryoScope time-lapse incubator may result in serious injury to the user.
- The EmbryoScope time-lapse incubator is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- It is the user's responsibility to validate the performance of the EmbryoScope time-lapse incubator by performing regular quality control checks on the temperature, CO₂ and O₂* levels.
* Only if the clinic incubates with reduced O₂ concentration.
- During initial start-up and after an incubator shutdown, always validate the gas and temperature levels using calibrated external validation devices as detailed in the EmbryoScope user manual. Do NOT rely solely on values displayed on the incubator control panel.

INSTALLATION AND MAINTENANCE

- Installation and repair of the EmbryoScope time-lapse incubator may only be carried out by a person certified by Vitrolife. The EmbryoScope time-lapse incubator must remain at the location where it was installed. If an EmbryoScope time-lapse incubator is disconnected and/or moved without supervision by a person certified by Vitrolife, the EmbryoScope time-lapse incubator will no longer be approved for clinical use and the warranty may be voided.
- If the EmbryoScope time-lapse incubator or parts of it are modified, appropriate inspection and testing must be conducted by a person certified by Vitrolife to ensure continued safe use.
- When cleaning and disinfecting the EmbryoScope time-lapse incubator, always use the prescribed chemical agents as specified in section 8 of the EmbryoScope user manual.

TRANSPORTATION AND RELOCATION OF THE EMBRYOSCOPE TIME-LAPSE INCUBATOR

- While the EmbryoScope time-lapse incubator is still in the shipping boxes, it must only be moved by using a lift truck or a pallet lifter. Do NOT open the shipping boxes without the presence of a person certified by Vitrolife.
- When the EmbryoScope time-lapse incubator has been unpacked, it must only be moved by two persons supporting the device underneath the left and right sides and only under the supervision of a person certified by Vitrolife.

CONNECTION TO EXTERNAL EQUIPMENT (EN 60601-1 MEDICAL ELECTRICAL EQUIPMENT – PART 1)

- External equipment intended for connection to signal input, signal output or other connectors must comply with the relevant IEC standard (i.e. EN 60601-1:2006 – Part 1 for medical electrical equipment). In addition, all such combinations – systems – must comply with the standard EN 60601-1:2015 – Part 2, General requirements for basic safety and essential performance. Equipment not complying with EN 60601-1:2006 – Part 1 must be kept outside the patient environment, i.e. at least 1.5 m from the patient or the patient support.
- Any person who connects external equipment to signal input, signal output or other connectors has formed a system and is therefore responsible for ensuring that the system complies with the requirements of EN 60601-1:2006 – Part 1. If in doubt, contact a qualified medical technician or your local representative.

ELECTROMAGNETIC COMPABILITY

- The EmbryoScope time-lapse incubator has been tested and found to comply with the limits for medical devices set out in the IEC 60601-1-2 Edition 4.0 for electromagnetic compatibility. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Compliance with IEC 60601-1-2 Edition 4.0 ensures compatibility when the EmbryoScope time-lapse incubator is placed at a minimum distance to nearby instruments. If the EmbryoScope time-lapse incubator is placed close to other instruments, it is necessary to observe that the performance of all instruments remains unaffected by the placement.

The EmbryoScope time-lapse incubator generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- a) Reorient or relocate the receiving device.
- b) Increase the separation between the equipment.
- c) Connect the equipment to an outlet on a circuit different from that to which the other device(s) are connected.

Consult the manufacturer, its representative or its dealer for help.

WARNING

- The use of accessories, transducers and cables other than those specified, with the exemption of transducers and cables sold by the manufacturer of the system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.
- The EmbryoScope time-lapse incubator should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the incubator should be observed to verify normal operation in the configuration in which it will be used.

CONFIDENTIALITY

- All identification numbers, names and treatment data presented in this manual are fictional.

LIMITED WARRANTY

- Vitrolife warrants the EmbryoScope time-lapse incubator to be free from defects in materials and workmanship for a period of one (1) year from the first installation date.

The limited warranty will terminate immediately if installation, maintenance, repair or relocation of the time-lapse incubator is carried out by other than Vitrolife-certified personnel.

The limited warranty does not apply to damage resulting from:

- a) failure to perform routine maintenance in accordance with the EmbryoScope user manual;
- b) accident, abuse, misuse or misapplication of the time-lapse incubator;
- c) use and operation that does not comply with instructions provided in the EmbryoScope user manual; or
- d) normal wear and tear.

GENERAL CYBERSECURITY RECOMMENDATIONS

- Users are advised and expected to take the following measures to reduce cybersecurity risk in order to ensure that the device will work as designed in the intended user environment:
 - Ensure that personnel are properly trained in cybersecurity awareness
 - Prevent physical access to the equipment by unauthorized users.
- Users must inform Vitrolife A/S without any undue delay upon becoming aware of a cybersecurity vulnerability incident or any suspected security events.
- For details about how to reduce cybersecurity risk, please refer to the separate guide on this subject provided by Vitrolife.

1.2 Important notes

NOTE – EXACT INSEMINATION TIME

- When a new EmbryoSlide culture dish is inserted, it is important to enter the exact insemination time and date as all subsequent events such as cell divisions will be related to the time of insemination. Entering an incorrect time and date will thus compromise the quality of your data.

NOTE – AUTO-FOCUS PROCEDURE

- If the auto-focus procedure did not find the best focused image, you can manually refocus the images by selecting the **Live View** option (home screen -> select the relevant EmbryoSlide culture dish by pressing the **Slide** tab -> press the image of the relevant well -> press the **Live** button).

NOTE – LIVE VIEW

- The automatic image acquisition is stopped in **Live** view during refocusing, adjustment of focal planes or adjustment of exposure time. The image acquisition will automatically restart after 30 minutes if you leave the EmbryoScope time-lapse incubator inactive in **Live** mode. The time period until the image acquisition is automatically resumed will be 30 minutes, even if you have set up the EmbryoScope time-lapse incubator to produce images every 10 minutes. You may, however, manually restart the image acquisition without any delay by returning the EmbryoScope time-lapse incubator to the embryo overview screen.
- If you adjust any of the camera settings in **Live** mode, the new settings are universally applied to all wells and EmbryoSlide culture dishes.
- When you have opened the **Live** view without working actively on the screen for two minutes, the light will automatically be turned off to prevent the embryo from being excessively exposed to the light. In this case, a red note will appear on the screen with the following text: "Camera light has been turned off. Press any key or button to re-activate".

NOTE – PAUSING EMBRYOSLIDE CULTURE DISHES

- While an EmbryoSlide culture dish is paused, no time-lapse images are acquired from the remaining EmbryoSlide culture dishes.
- If an EmbryoSlide culture dish has been paused for more than one hour, the EmbryoScope time-lapse incubator will issue an alarm. This audible alarm can be temporarily paused by pressing **Reset alarm** on the incubator touch screen.

NOTE – DATA STORAGE

- When you have more than 5 GB free storage space, files older than 50 days are automatically deleted from the **Scope Data** folder.
- When you have less than 5 GB free storage space, your hard drive is starting to fill up. In this case, ALL files older than seven days will be deleted. The oldest files will be deleted first until the amount of free storage space is back to more than 5 GB.
- ALL of the data are stored either on the PC running the EmbryoViewer software or on the ES server from which they will not be deleted.

1.3 Intended use

The EmbryoScope incubator is intended for the incubation of embryos as part of fertility treatment.

1.4 Indications for use

EmbryoScope consists of the following devices with the following indications for use:

The EmbryoScope incubator provides an environment with controlled temperature and CO₂ levels for the development of embryos at or near body temperature. Use of the EmbryoScope incubator is limited to five days (120 hours) covering the time from post-insemination to day five of development.

The EmbryoSlide culture dish is intended for preparing, storing and transferring human embryos. The EmbryoSlide culture dish must be used together with the EmbryoScope incubator.

The EmbryoViewer software is intended for displaying and comparing images generated by the EmbryoScope incubator. The software includes a user annotation function for capturing information on embryo development parameters as well as a user-defined modeling function that allows the user to combine annotated information on embryo development parameters to aid in embryo selection. The EmbryoViewer software does not control any hardware components in the EmbryoScope incubator.

The ES server software is intended for storing, archiving and transferring data. In addition, the software includes functions for managing models and performing calculations based on image data and embryo development parameters.

The EmbryoScope incubator, the EmbryoViewer software and the ES server software must be used together to export embryo images from the EmbryoScope incubator. The EmbryoViewer software and ES server software must be used together to analyze the embryo images.

1.5 Intended users

Embryologists, other laboratory personnel and clinic staff at IVF clinics trained by Vitrolife A/S-certified instructors.

1.6 Clinical benefits

- Improved embryo development
- Improved implantation/pregnancy rate
- Reduced pregnancy loss rate.

2 Overview of the EmbryoScope time-lapse incubator

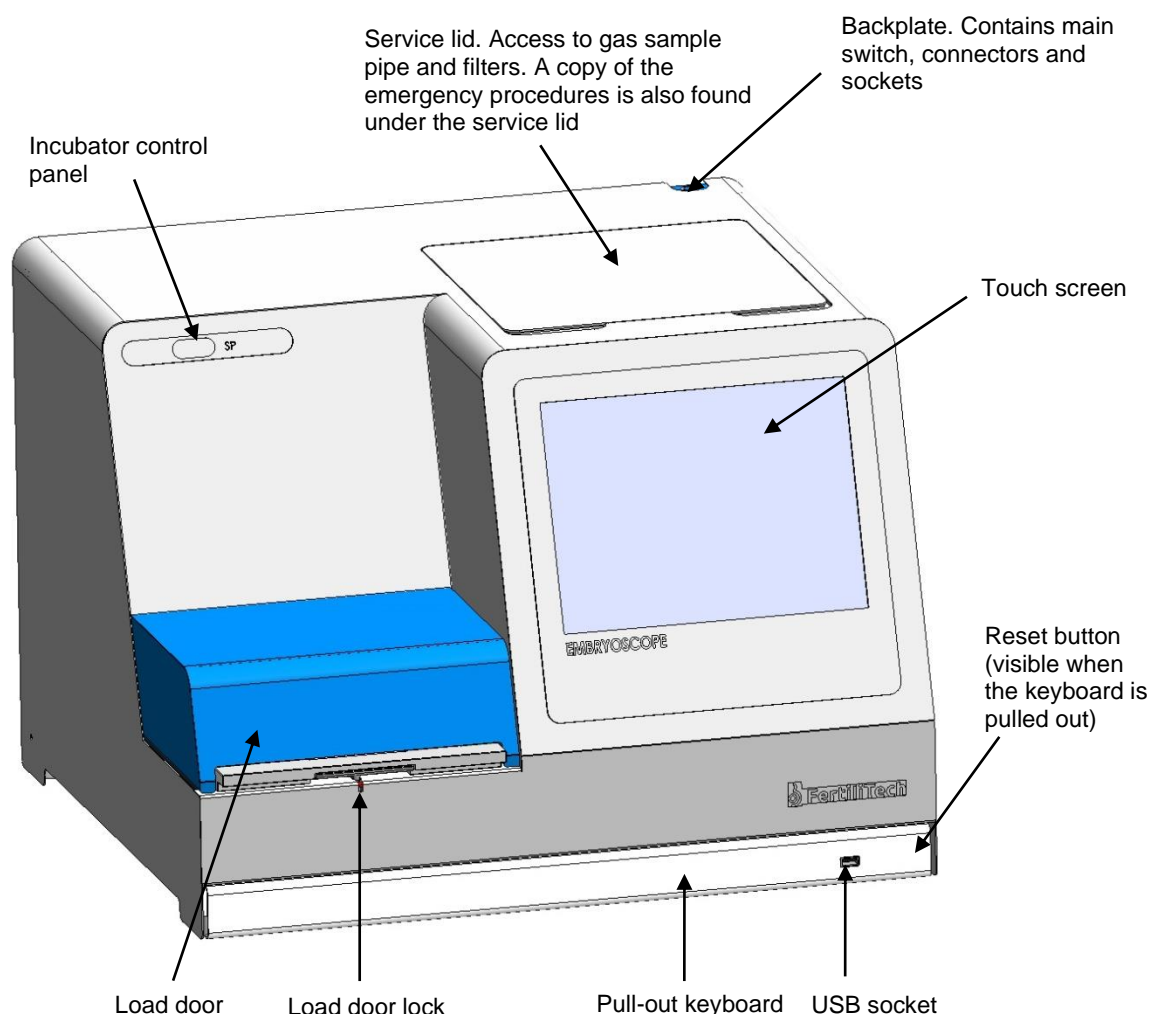


Image series are analyzed automatically in real time with proprietary software. Blastomere activity is a numerical parameter that reflects the amount of movement that has occurred between two consecutive frames in the time-lapse image series. The blastomere activity has NO DIAGNOSTIC USE, but can be used to aid users in identifying areas in the time series where events of interest may be occurring. No operator input is required, and the output is available at any time during incubation.

2.1 Installation and required conditions

The incubator must be set up in accordance with the installation checklist. It should not be moved or disconnected by persons who are not certified by Vitrolife.

Installation requirements:

- Clean room with a stable temperature between 20°C and 30°C.
- Sturdy table with approximately 1.0 x 0.6 m of bench space.
- A minimum distance of 150 mm between the back wall of the EmbryoScope time-lapse incubator and any solid object.
- Optional: Uninterruptible power supply (UPS), min. 300 W, with proper grounding.
- Residual-current device (RCD) or ground fault (circuit) interrupter (GFI/GFCI).
- Specification of attachment plug for connection to the alternate voltage: NEMA 5-15 (hospital grade).
- CO₂ gas supply with pressure regulator capable of providing stable output of CO₂ between 0.6 - 1 bar above ambient.
- N₂ gas supply with pressure regulator capable of providing stable output of N₂ between 0.6 - 1 bar above ambient.
- Medical electrical equipment requires special precautions regarding EMC and must be installed and put into service according to the EMC information provided.

NOTE
<ul style="list-style-type: none">• No cooling facilities are present in the embryo chamber. If the temperature rises above the specified limits, the temperature inside the embryo chamber will therefore reach at least ambient temperature.• It is strongly recommended, although not required, to connect the incubator to an uninterruptible power supply (UPS) with earth connector to ensure stable operating conditions in case of power failure. Any UPS connected to the EmbryoScope incubator must comply with the following directives and harmonized standards:<ul style="list-style-type: none">○ Low Voltage Directive 2014/35/EU○ Electromagnetic Compatibility Directive 2014/30/EU○ EN 62040-1:2009 Uninterruptible power systems (UPS) – Part 1: General and safety requirements for UPS○ EN 62040-2:2006 Uninterruptible power systems (UPS) – Part 2: Electromagnetic compatibility (EMC) requirements.

2.2 Starting up the EmbryoScope time-lapse incubator

The EmbryoScope time-lapse incubator should be turned on at least three hours before use to ensure temperature equilibration throughout the time-lapse incubator. Please ensure that the EmbryoScope time-lapse incubator is grounded through the power connector, that the gas connections are not leaking, and that the gas reservoir is full. Furthermore, you should periodically check the residual pressure of the gas cylinders and replace the CO₂ or N₂ cylinders if the pressure drops below 40 bars. The back pressure in the connecting tubes should not exceed 1 bar or drop below 0.6 bar.

2.3 Shutting down the EmbryoScope time-lapse incubator

In order to shut down the EmbryoScope time-lapse incubator (e.g. for service or cleaning), follow the procedure described below.

NOTE
<ul style="list-style-type: none">In case of an emergency, please follow the procedure described in section 10.

1. Remove all EmbryoSlide culture dishes from the EmbryoScope time-lapse incubator (see the procedure in section 6.6).
2. Press the **Shutdown** button on the home screen.
3. Select **Close Computer** in the presented dialog box. This turns off the PC of the EmbryoScope time-lapse incubator (the incubator itself will continue to run).
4. Press **OK** in the presented dialog box.
5. In order to turn off the incubator, use the main power switch located at the back of the EmbryoScope time-lapse incubator. See also section 4.

NOTE
<ul style="list-style-type: none">If the EmbryoScope time-lapse incubator is left with the desktop open for an extended period of time, the software embedded in the incubator is not running and no time-lapse images will be acquired. In this case, the incubator will activate a warning information signal.

NOTE
<ul style="list-style-type: none">The software of the EmbryoScope time-lapse incubator and Microsoft Windows should always be shut down correctly before the power is switched off.

3 Restarting the integrated PC

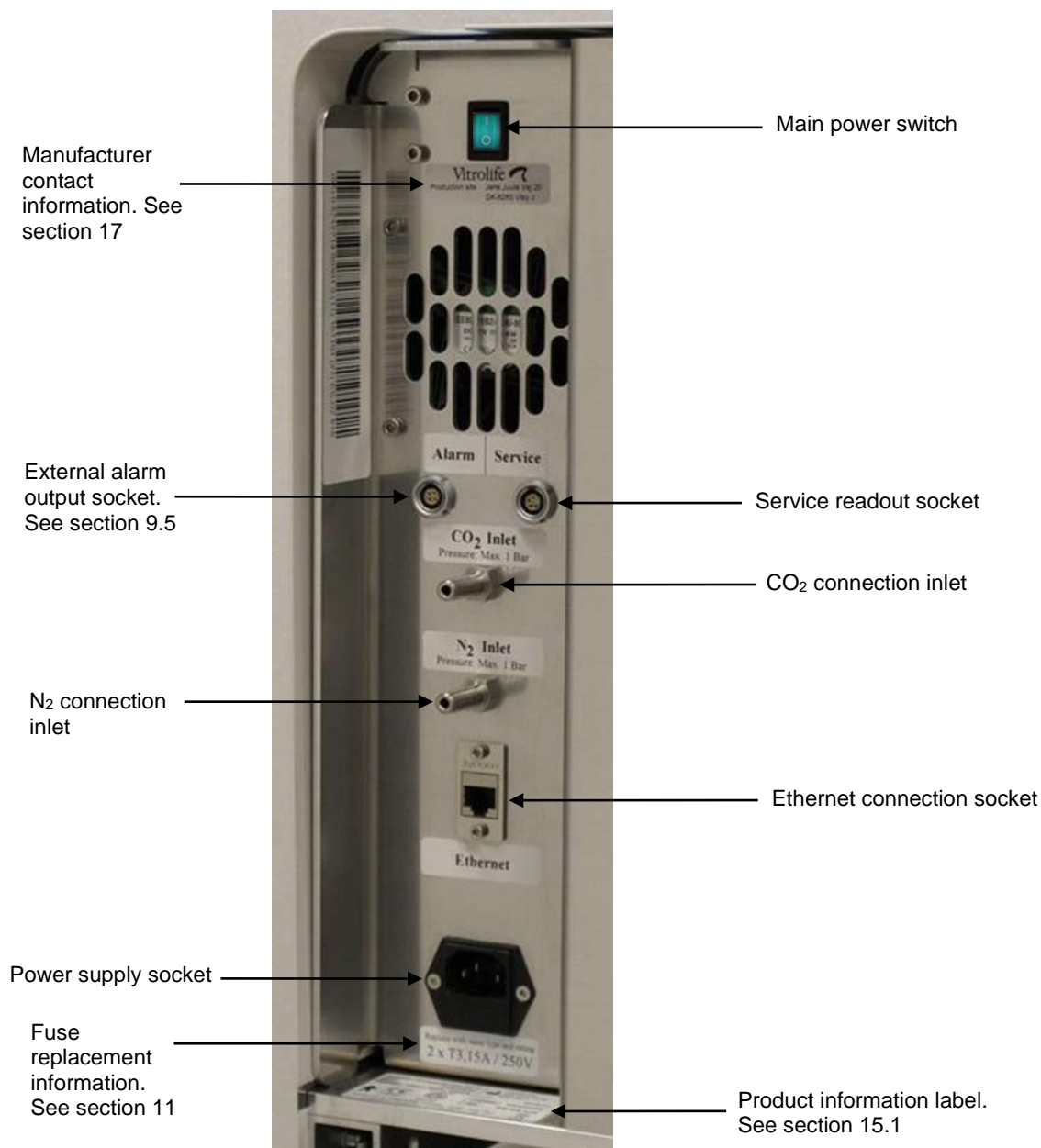
In some cases, it will be necessary to restart the PC that is integrated in the EmbryoScope time-lapse incubator, e.g. if an error condition occurs.

To restart the PC:

1. Pull out the keyboard at the bottom of the EmbryoScope time-lapse incubator.
2. Use a pointed object such as a pencil or a ballpoint to press the small red button available to the right of the keyboard (see the illustration in section 2). The PC will now shut down.
3. Press the red button again to restart the PC.

4 Connections to supporting systems

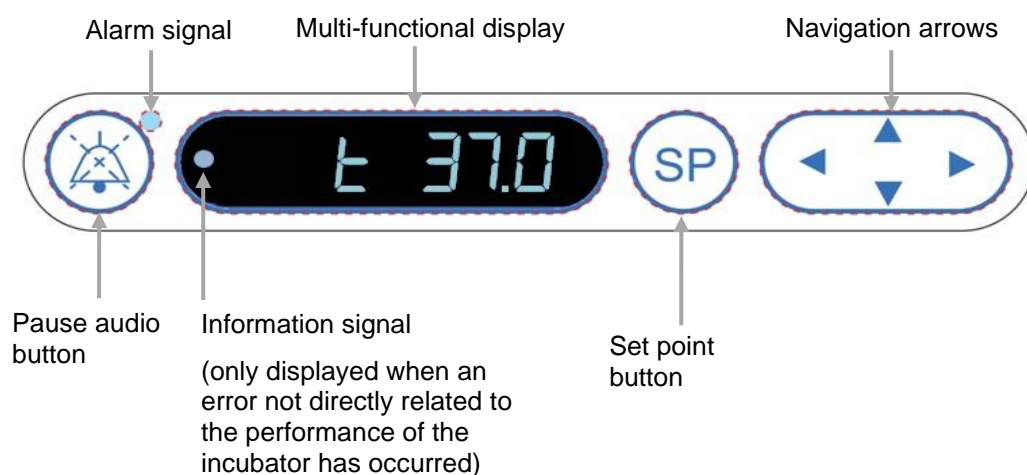
All connectors and sockets are found at the back of the EmbryoScope time-lapse incubator. Connectors and sockets should only be used by a person certified by Vitrolife during installation. Operators should never use or attach any tubing/wiring to the panel.



5 The incubator

5.1 The incubator control panel

The incubator control panel is located in the upper left corner of the EmbryoScope time-lapse incubator:

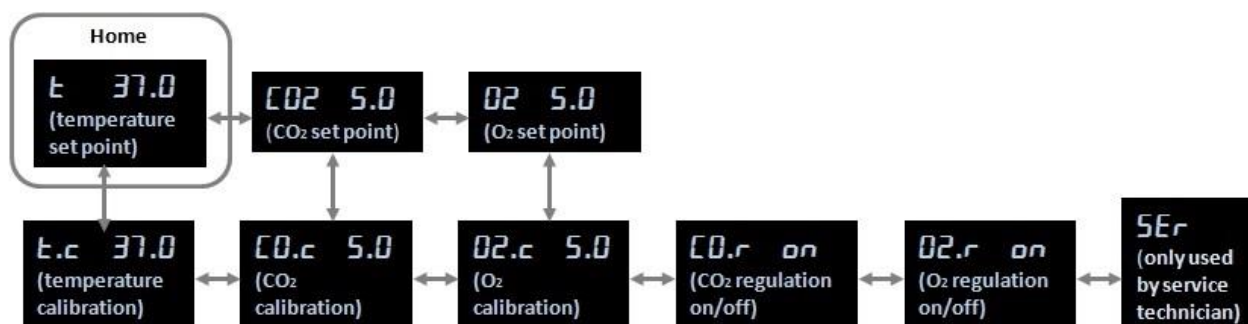


The control panel is used for:


- Pausing audible warning alarms issued by the EmbryoScope time-lapse incubator (using the pause audio button)
- Inspecting a range of incubation parameters such as temperature, CO₂ concentration, O₂ concentration, etc. (from the set point menu)
- Changing the set point of the incubation parameters (from the set point menu)
- Calibrating the EmbryoScope time-lapse incubator (from the calibration menu)
- Turning on or off CO₂ and O₂ regulation (from the calibration menu).

5.1.1 Overview of menu items accessible from the control panel

The incubator control panel provides access to two separate menus: The set point menu and the calibration menu.



Overview of menu items available from incubator control panel

To navigate from the set point menu to the calibration menu, press the down arrow for about three seconds. To navigate back from the calibration menu to the set point menu, press the up arrow for about three seconds. While the menu is being changed, the display will flash:  until the change of menu is complete.

To navigate back and forth between the items available in each menu, press the left or right arrow. For example, if the temperature is currently displayed in the set point menu and you want to inspect the CO₂ concentration, press the right arrow once. If you afterwards want to return to the temperature, press the left arrow once.

5.2 Locking or unlocking the incubator control panel

The control panel can be locked to ensure that no parameters are inadvertently changed. When the control panel is locked, you cannot change the set point or calibrate the parameters; neither can you turn on or off CO₂ or O₂ regulation.

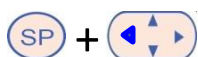
If you attempt to change any of the parameters when the panel is locked, the display will show:



to indicate that a lock is active and needs to be removed before the action can be performed.

To lock the control panel:

Simultaneously press and hold the **SP** button and the left arrow for about three seconds:





The display will briefly show:  to indicate that the control panel has been locked.


To unlock the control panel:

Simultaneously press and hold the **SP** button and the right arrow for about three seconds:



The display will briefly show:  to indicate that the control panel has been unlocked.

5.3 Temporarily pausing audible warning alarms


To pause the audible alarm signal for three minutes, press the pause audio button: . Pausing the warning alarm will not affect the LED, which will continue to flash until the problem that caused the warning alarm has been solved.




5.4 Incubator temperature




5.4.1 Changing the temperature set point

1. In the set point menu, make sure that the display shows the incubator temperature. If this is not the case, navigate to the temperature menu item by pressing the right or left arrow



until the current temperature set point is displayed:  (temperature menu item – the set point is: 37°C).

2. Press the  button. The display will start to alternate between showing  (temperature menu item – the set point is: 37°C) and  (set point menu is active – the set point is: 37°C). This indicates that you are about to adjust the temperature set point.

3. While still holding the  button, press the up or down arrow  to increase or decrease the set point. Each time you press the up or down arrow once, you will either increase or decrease the set point by 0.1°C.
4. Release the  button to save the new setting.

5.4.2 Validating the temperature

The EmbryoScope time-lapse incubator must have been turned on for at least three hours before the temperature is validated. The room temperature must be equivalent to normal laboratory temperature. The temperature validation is performed by measuring the temperature in the culture dish holder using a temperature probe connected to a high-precision thermometer.

NOTE

- While performing this procedure, be very careful not to inadvertently touch or push the EmbryoSlide culture dish(es) present in the culture dish holder.
- Before you start, make sure that the high-precision thermometer is calibrated according to the manufacturer's specifications.

Follow this procedure to validate the temperature:

1. Press **Check** on the touch screen of the EmbryoScope time-lapse incubator. The culture dish holder will move to a position that enables you to perform an external temperature measurement.
2. Open the load door to the embryo chamber.
3. Insert the temperature probe in the small socket available at the base of the culture dish holder (see the picture below). The temperature probe must be completely inserted into the socket to measure the core temperature of the culture dish holder correctly.



4. Leave the thin part of the cable inside the embryo chamber.

5. Carefully close the load door (avoid closing it on the thin cable).
6. Let the temperature probe equilibrate for approximately ten minutes.

The core temperature of the culture dish holder measured by the temperature probe is 0.2°C higher than the temperature at the bottom of the microwell where the embryos reside as specified in the following table:

Core temperature of the culture dish holder measured by the external probe (°C)	Temperature at the bottom of the microwell (medium temperature, °C)
37.00	36.80
37.10	36.90
37.20	37.00
37.30	37.10
37.40	37.20
37.50	37.30

5.4.3 Calibrating the temperature

The EmbryoScope time-lapse incubator must have been turned on for at least three hours to achieve full equilibrium before the temperature is calibrated. The room temperature must be equivalent to normal laboratory temperature.

If the external temperature measured by using the high-precision thermometer deviates from the currently displayed temperature, you can calibrate the temperature from the control panel.

Example:

- The temperature measured by using the high-precision thermometer is 37.3°C.
- The set point is 37.0°C.
- The temperature currently displayed on the incubator control panel is 37.0°C.
- Calibrate the displayed temperature to be $37.3^{\circ}\text{C} - 0.2^{\circ}\text{C} = 37.1^{\circ}\text{C}$.

It is necessary to deduct 0.2°C from the measured temperature to compensate for the discrepancy between the measured temperature and the actual temperature at the bottom of the microwell (see also the following NOTE).













- Verify that the temperature measured by the high-precision thermometer settles at 37.2°C ($37.0^{\circ}\text{C} + \text{the } 0.2^{\circ}\text{C} \text{ difference between the measured temperature and the actual temperature at the bottom of the microwells}$).

The display on the incubator control panel will change back from 37.1°C to 37.0°C.


NOTE

- The core temperature of the culture dish holder measured by the high-precision thermometer is 0.2°C higher than the temperature at the bottom of the microwell where the embryo resides.
- You should therefore adjust the temperature on the display to match the reading made by the external thermometer minus 0.2°C (see also the preceding table for examples of the calibration temperature for various readings).

Follow this procedure to calibrate the temperature:






1. In the set point menu, navigate to the temperature menu item  (temperature menu item – the set point is: 37°C) by pressing either the right or the left arrow .
2. Press and hold the down arrow  until the display stops flashing . When the change of menu is successful, the display will show  (temperature calibration – the calibration is: 37°C).
3. Press and hold the  button. The display will now alternate between showing  and  (calibration menu is active – the calibration is: 37.0°C). This indicates that you are about to calibrate the temperature.
4. While still holding the  button, use the up or down arrow  to increase or decrease the temperature calibration to the desired level. Each time you press the arrow, you increase or decrease the temperature by 0.05°C.
5. Release the  button to save the calibration.
6. Press and hold the up arrow  for three seconds to return to the temperature menu item in the set point menu.
7. Wait at least ten minutes until the temperature is stable. Then validate the temperature after calibration. You can track the temperature by pressing the **Temperature** button on the touch screen of the EmbryoScope time-lapse incubator.

NOTE

- Always validate the incubator temperature after calibration.
- It is not possible to calibrate the temperature in excess of $\pm 3.0^{\circ}\text{C}$. If you attempt to calibrate the temperature more than this as compared with your starting point, the control panel will display **Err** when you press the  button and the up/down arrow simultaneously. This e.g. means that if you have once calibrated the temperature by $+ 0.3^{\circ}\text{C}$, the maximum temperature increase during your next temperature calibration will be $+ 2.7^{\circ}\text{C}$. The maximum temperature reduction will then be $- 3.3^{\circ}\text{C}$ ($3.0^{\circ}\text{C} + 0.3^{\circ}\text{C}$).

5.5 Incubator CO₂ concentration

5.5.1 Changing the CO₂ set point

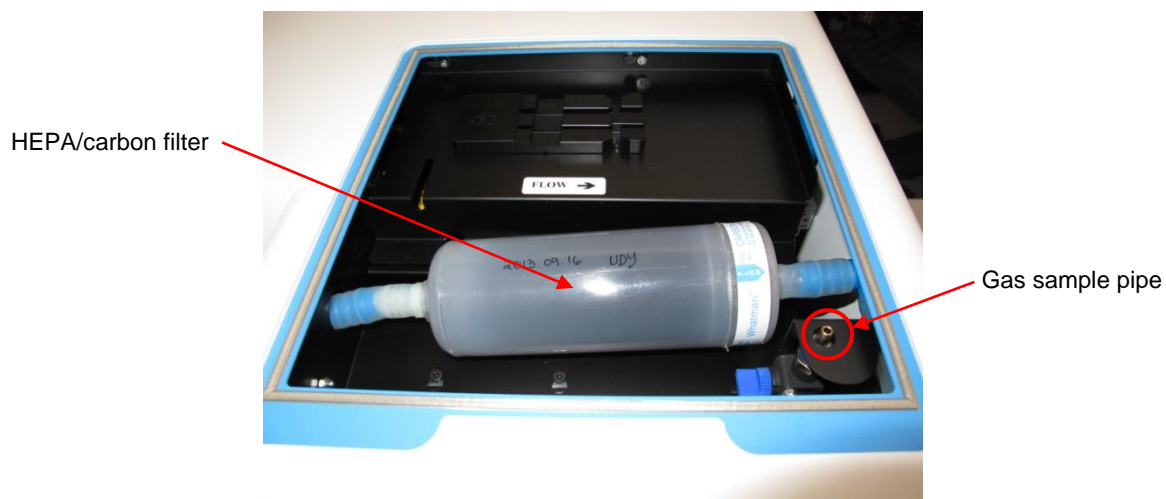
1. In the set point menu, check whether the display shows the CO₂ concentration. If this is not the case, navigate to the CO₂ menu item using the right or left arrow  until the CO₂ concentration is displayed: **CO2 5.0** (CO₂ menu item – the set point is: 5.0).
2. Press and hold the  button. The display will now alternate between showing **CO2 5.0** (CO₂ menu item – the set point is: 5.0) and **SP 5.0** (set point menu is active – the set point is: 5.0). This indicates that you are about to adjust the CO₂ set point.
3. While still holding the  button, press either the up or the down arrow  to increase or decrease the CO₂ set point. Each time you press the up or down arrow once, you will either increase or decrease the set point by 0.1%.
4. Release the  button to save the new setting.

5.5.2 Validating the CO₂ concentration

NOTE

- Before the CO₂ concentration is validated, the EmbryoScope time-lapse incubator must have been turned on for at least two hours with the appropriate gasses connected to ensure that full equilibrium is attained. The room temperature must be equivalent to normal laboratory temperature.
- Before you start, please make sure that the gas analyzer is calibrated according to the manufacturer's specifications.

1. Switch on the gas analyzer used for measuring the CO₂ concentration.
2. Remove the service lid on the EmbryoScope time-lapse incubator.
3. Attach the tube from the gas analyzer to the gas sample pipe.













4. Open the valve by turning the lever towards you until the lever is in upright position.
5. Press **Check** on the touch screen of the EmbryoScope time-lapse incubator.
6. Measure the CO₂ concentration two or three times or until the measurement is stable.
7. If the measured CO₂ concentration deviates from the set point, you need to calibrate the CO₂ concentration as described in section 5.5.3.





5.5.3 Calibrating the CO₂ concentration

NOTE


- Attaching a CO₂ calibration device with a strong internal pump may interfere with the internal gas control system inside the EmbryoScope time-lapse incubator. Therefore, do not use a calibration device that absorbs more than 0.5 l/min.

- In the set point menu, navigate to the CO₂ menu item by pressing either the right or the left arrow  until the CO₂ concentration is displayed:  (CO₂ menu item – the set point is: 5.0).
- Press and hold the down arrow for three seconds  until the display stops flashing  to enter the calibration menu. When the change of menu is successful, the display will show:  (CO₂ calibration – the calibration is: 5.0).
- Press and hold the  button. The display will now alternate between showing  (CO₂ calibration – 5.0) and  (calibration menu is active – the calibration is: 5.0). This indicates that you are about to calibrate the CO₂ concentration.
- While still holding the  button, press either the up or the down arrow  to increase or decrease the CO₂ concentration. The value of the CO₂ concentration is adjusted by 0.1% each time you press the up or down arrow once.

You should adjust the CO₂ concentration to match the reading on the external gas analyzer, i.e. if the gas analyzer reads 5.6%, you need to adjust the value on the display to 5.6.






- Release the  button to save the calibration.
- Press and hold the up arrow  until the display stops flashing  to enter the calibration menu. When the change of menu is successful, the display will show:  (CO₂ set point – the set point is: 5.0).
- Wait 10-20 minutes until the CO₂ concentration is stable, and then validate the concentration by following the procedure described in section 5.5.2. You can also monitor the CO₂ concentration by pressing the **CO₂** button on the touch screen of the EmbryoScope time-lapse incubator.

NOTE

- Always validate the CO₂ concentration after calibration by performing several measurements.
- It is not possible to calibrate the CO₂ concentration in excess of +/- 2%. If you attempt to calibrate the concentration more than this as compared with your starting point, the control panel will display **Err** when you press the  button and the up/down arrow simultaneously. This e.g. means that if you have once calibrated the concentration by + 0.5%, the maximum CO₂ increase during your next calibration will be + 1.5%. The maximum CO₂ reduction will then be - 2.5% (2% + 0.5%).

5.6 Incubator O₂ concentration

5.6.1 Changing the O₂ set point

1. In the set point menu, verify that the display shows the O₂ concentration. If this is not the case, navigate to the O₂ menu item by pressing either the right or the left arrow  until the O₂ concentration is displayed: **02 5.0** (O₂ menu item – the set point is: 5.0).
2. Press and hold the  button. The display will now alternate between showing **02 5.0** (O₂ menu item – the set point is: 5.0) and **SP 5.0** (set point menu is active – the set point is: 5.0). This indicates that you are about to change the O₂ set point.
3. While still holding the  button, press the up or the down arrow  to increase or decrease the O₂ set point. Each time you press the up or down arrow once, you will either increase or decrease the set point by 0.1%.
4. Release the  button to save the new setting.


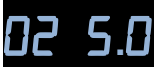








5.6.2 Validating the O₂ concentration

To validate the O₂ concentration, follow the procedure in section 5.5.2.



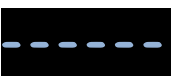

5.6.3 Calibrating the O₂ concentration

NOTE

- Attaching an O₂ calibration device with a strong internal pump may interfere with the internal gas control system inside the EmbryoScope time-lapse incubator. Therefore, do not use a calibration device that absorbs more than 0.5 l/min.



- In the set point menu, press the right or the left arrow  until the O₂ menu item is displayed:  (O₂ menu item – the set point is: 5.0).
- Press and hold the down arrow for three seconds  until the display stops flashing  to enter the calibration menu. When the change of menu is successful, the display will show  (O₂ calibration – the calibration is: 5.0).
- Press and hold the  button. The display will now alternate between showing  (O₂ calibration – the calibration is: 5.0) and  (calibration – 5.0). This indicates that you are about to calibrate the O₂ concentration.
- While still holding the  button, press either the up or the down arrow  to increase or decrease the O₂ calibration. The value of the O₂ concentration is adjusted by 0.1% each time you press the up or down arrow once.

You should adjust the O₂ concentration to match the reading on the external gas analyzer, i.e. if the gas analyzer reads 5.6%, you need to adjust the value on the display to 5.6.

- Release the  button to save the calibration.
- Press and hold the up arrow  until the display stops flashing  to return to the set point menu. When the change of menu is successful, the display will show:  (O₂ menu item – the set point is: 5.0).

7. Wait 10-20 minutes until the O₂ concentration is stable, and then validate the concentration by following the procedure described in section 5.5.2. You can also monitor the O₂ concentration by pressing the O₂ button on the touch screen of the EmbryoScope time-lapse incubator.

NOTE

- Always validate the O₂ concentration after calibration by performing several measurements.
- It is not possible to calibrate the O₂ concentration in excess of +/- 3%. If you attempt to calibrate the concentration more than this as compared with your starting point, the control panel will display  when you press the  button and the up/down arrow simultaneously. This e.g. means that if you have once calibrated the concentration by + 0.5%, the maximum O₂ increase during your next calibration will be + 2.5%. The maximum O₂ reduction will then be - 3.5% (3% + 0.5%).

6 Operating the EmbryoScope time-lapse incubator

The EmbryoScope time-lapse incubator has an integrated industry-grade PC running Microsoft Windows. The PC controls all data acquisition functions, motors, camera, etc. The incubation conditions (temperature, CO₂ and O₂ concentration) are controlled by an independent unit. The incubation conditions are thus unaffected by software failures or failures in the operating system of the PC. An audible alarm will notify the user in case of a software failure or a failure of the operating system.

6.1 Start-up procedure

1. Turn on the EmbryoScope time-lapse incubator on the main switch (green switch at the back of the time-lapse incubator, upper left corner).
2. From the incubator control panel, check that the temperature and gas set points etc. are at the desired levels (see sections 5.4.1, 5.5.1 and 5.6.1).
3. Wait for the Windows operating system and the software of the EmbryoScope time-lapse incubator to start automatically.

Once everything has been started and checked, you are presented with the welcome screen.

The **Start** button will be active.



4. Press the **Start** button.
5. After three hours, validate the temperature and gas levels using your thermometer and gas analyzer (see also sections 5.4.2, 5.5.2 and 5.6.2).

When you have confirmed that temperature and gas are at the desired levels, the EmbryoScope time-lapse incubator is ready for insertion of an EmbryoSlide culture dish (see also section 6.3).

WARNING

- During initial start-up and after an incubator shutdown, always validate the gas and temperature levels using calibrated external validation devices as detailed in the EmbryoScope user manual. Do NOT rely solely on values displayed on the incubator control panel.

6.2 Resetting and calibrating the camera

To ensure that the two motors in the EmbryoScope time-lapse incubator move the culture dish holder correctly and in alignment with the camera, a camera reset and calibration is required in the following cases:

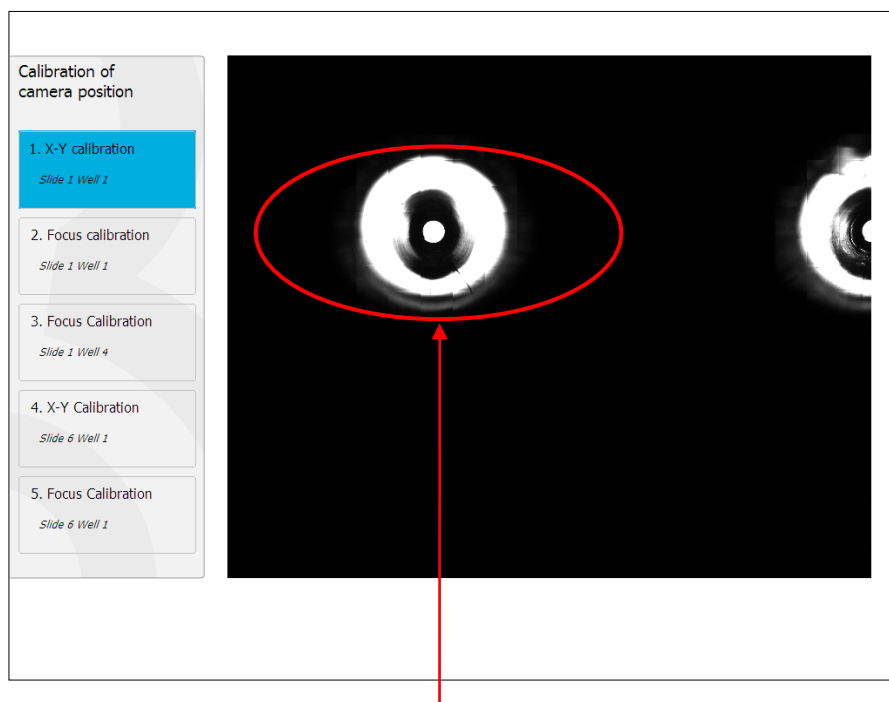
- Autofocus is not working appropriately.
- Wells are not centered.
- Cleaning or inspection has been carried out.
- The culture dish holder has been remounted.

Follow this procedure to reset and calibrate the camera:

1. Press **Shutdown** and then **Close Program**. The program shuts down, and the Windows desktop is displayed.
2. Restart the Scope_D program from the desktop and wait for the welcome screen to appear.
3. Press **Reset...** on the welcome screen.
4. Press **OK** when asked whether you want to change the instrument parameters.
5. Select **Standard** as adjustment method. Do not select the **Advanced** option. This option is only to be used by technicians certified by Vitrolife.

Do not press **OK** on the touch screen yet. This will cause the culture dish holder to move away from the loading position, and you will be unable to insert the EmbryoSlide culture dish.
6. Place an empty EmbryoSlide culture dish in position no. 1 of the culture dish holder. Make sure to place the EmbryoSlide culture dish correctly in the culture dish holder. Placing the culture dish incorrectly will adversely affect the efficiency of the autofocus procedure.
7. Press **OK** on the touch screen of the EmbryoScope time-lapse incubator.

8. When the image of well no. 1 is displayed, press the center of the well on the touch screen.



Well no. 1 of the culture dish in position no. 1

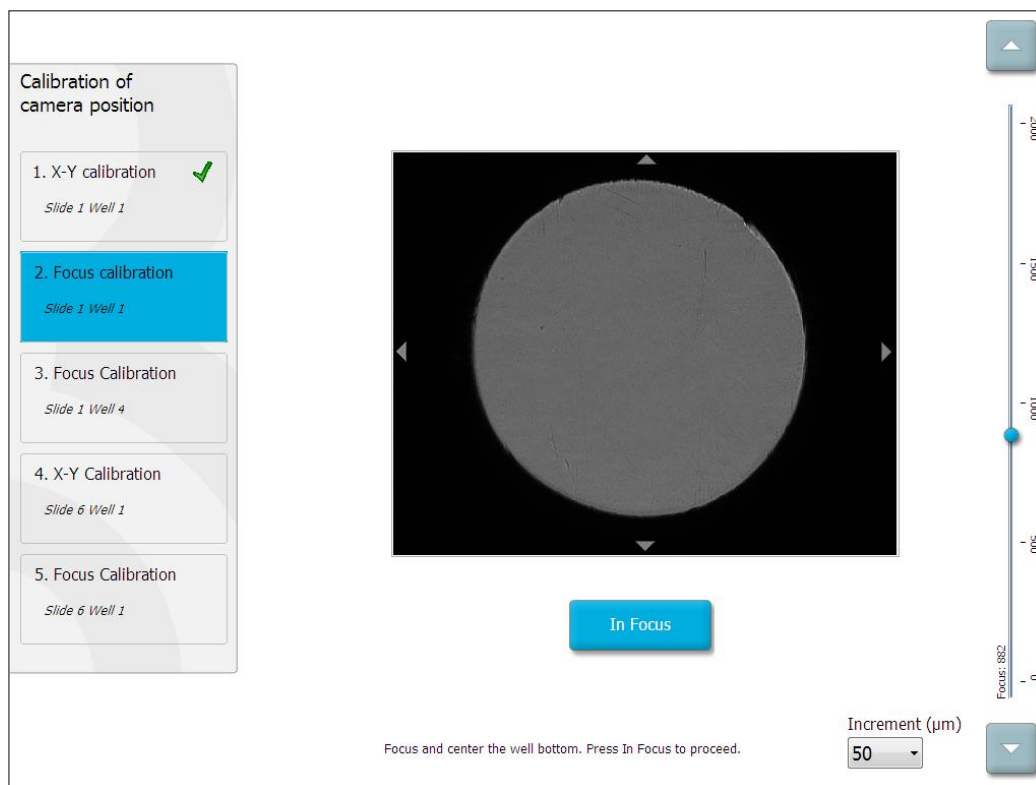
NOTE

- Camera calibration should always start with an image of well no. 1 in the EmbryoSlide culture dish. Check in the left pane that well no. 1 is highlighted. If this is not the case, a correct calibration cannot be performed.

9. Adjust the well until it is placed in the middle of the picture. Either use the adjustment arrows on the screen or drag the well to the center from the touch screen. Adjust the focal plane so that the bottom of the well is in focus, and press the **In Focus** button on the screen.

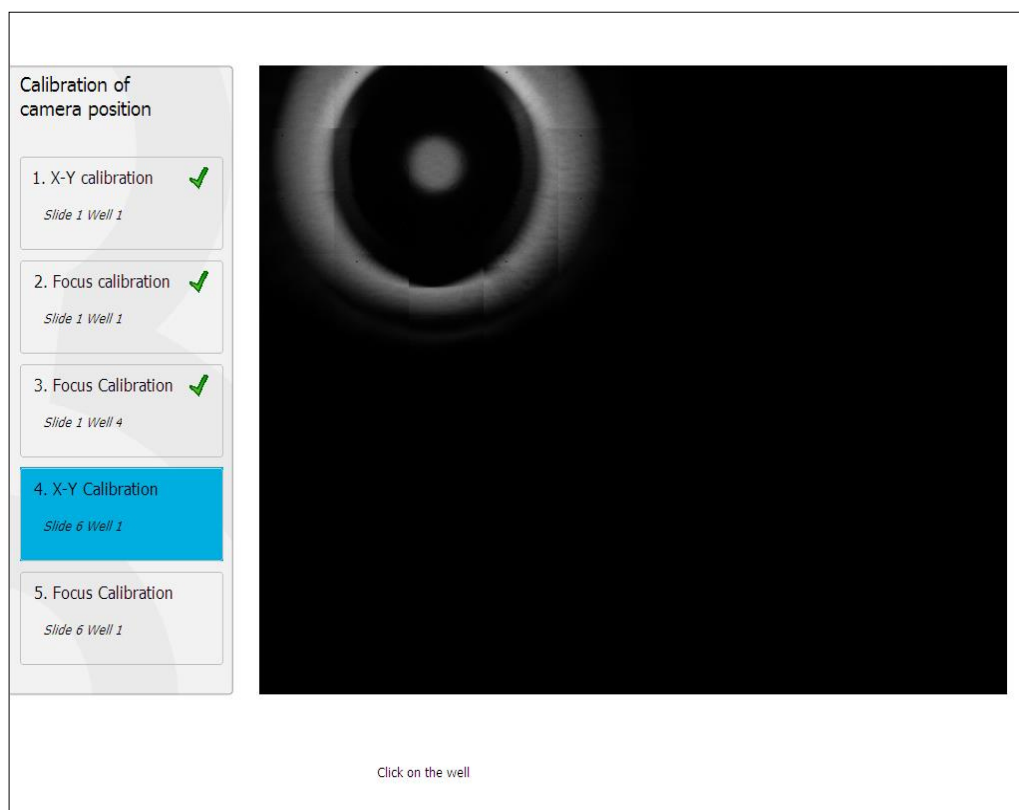


10. The image of EmbryoSlide culture dish no. 1, well no. 4 is displayed. Adjust the well until it is placed in the middle of the picture. Use either the adjustment arrows on the screen or the touch screen to drag the well to the center. Adjust the focal plane so that the bottom of the well is in focus, and press the **In Focus** button on the screen.



11. Follow the instructions given on the screen. Please make sure that you have removed the culture dish before you press **OK**. Pressing **OK** will cause the culture dish holder to move away from the loading position, and you will be unable to remove the EmbryoSlide culture dish.

12. Proceed with X-Y calibration and focus calibration of EmbryoSlide culture dish no. 6, well no. 1.



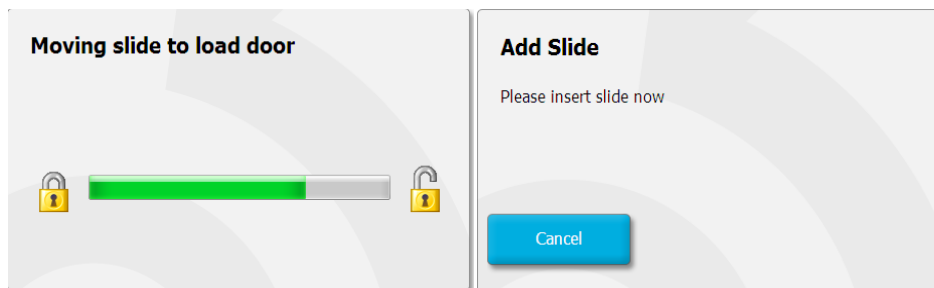
13. Follow the instructions given on the screen, and finish the reset procedure. Press **Yes** to save the new parameters.

The EmbryoScope time-lapse incubator has now been recalibrated and is ready to start. Proceed to section 6.3 to start an EmbryoSlide culture dish.

6.3 Starting an EmbryoSlide culture dish

Follow this procedure to start an EmbryoSlide culture dish:

1. On the home screen, press the **Add Slide** button.



NOTE

- EmbryoScope time-lapse incubators with a serial number lower than 100 do not have a lock indicator light in the load door cover.

2. Open the load door and place the EmbryoSlide culture dish in the accessible position of the holder.

The first culture dish is placed in position 1. Subsequent culture dishes should be placed in the next free positions. The EmbryoSlide culture dish should be inserted with the handling tail fin towards the front of the incubator.

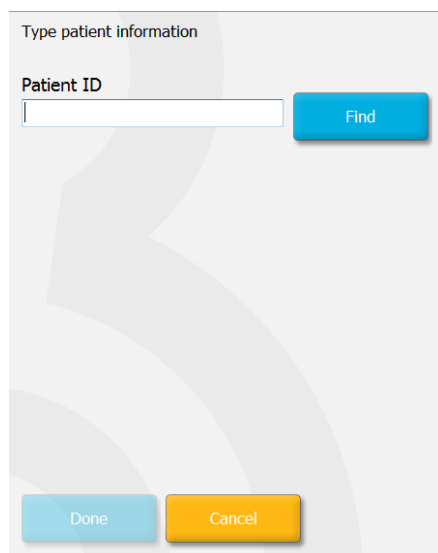
3. Close the load door and press **OK**.

The EmbryoSlide culture dish has now been inserted, and the patient and treatment information has automatically been registered.

Proceed to sections 6.3.1 and 6.3.2.

6.3.1 Associating an existing patient with a new EmbryoSlide culture dish

1. Enter the relevant patient ID, and press the **Find** button. Please be careful to select the correct patient ID.



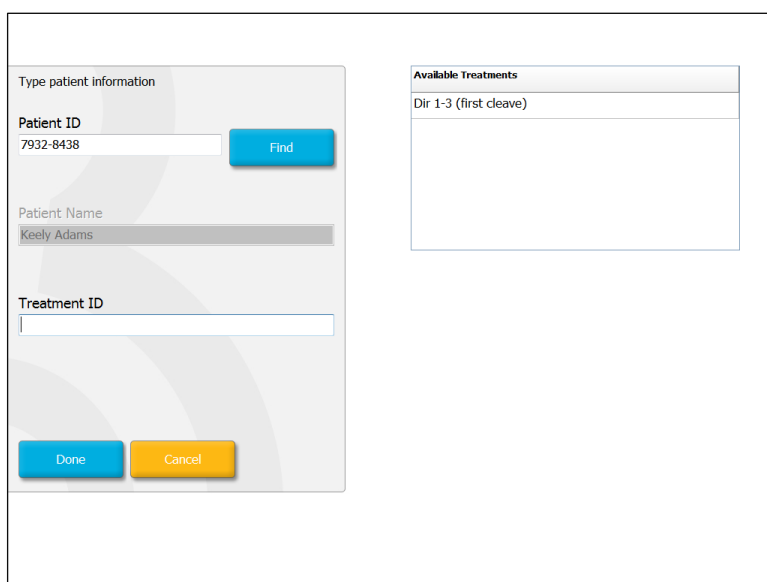
Type patient information

Patient ID

Find

Done Cancel

The patient name is retrieved from the database, and a list of available treatments associated with the patient is presented:



Type patient information

Patient ID

7932-8438

Find

Patient Name

Keely Adams

Treatment ID

Done Cancel

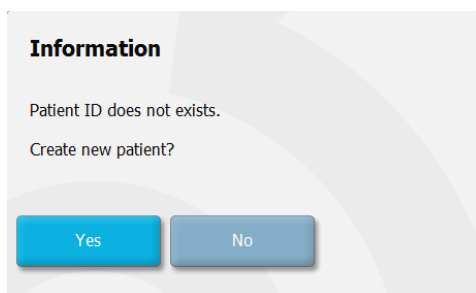
Available Treatments

Dir 1-3 (first cleave)

2. Select an existing treatment ID from the list of available treatments, or add a new treatment ID in the **Treatment ID** field.
3. Press **Done**. The EmbryoSlide details screen is now presented.

6.3.2 Creating a new patient on the EmbryoScope time-lapse incubator

1. Enter a patient ID in the **Patient ID** field and press **Find**. If the patient ID you have entered could not be retrieved from the database, this dialog box is displayed:



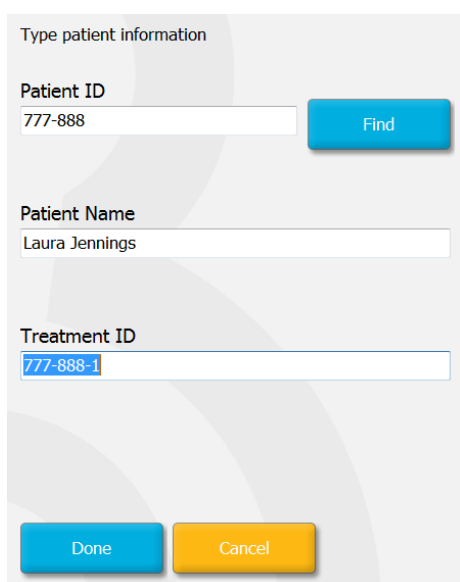
Information

Patient ID does not exists.

Create new patient?

Yes No

2. Press **Yes** to create a new patient. The **Type patient information** screen is now presented:



Type patient information

Patient ID
777-888 Find

Patient Name
Laura Jennings

Treatment ID
777-888-1

Done Cancel

3. Complete the **Patient Name** field.
4. Add a treatment ID in the **Treatment ID** field.
5. Press **Done**. The new patient is created and a treatment is added. On the EmbryoSlide details screen, you can enter additional data for the new patient and treatment.

6.4 Playing a time-lapse video

From the home screen -> **Slide** tab -> **Video** tab, you can play an embryo time-lapse video by pressing the right arrow button in the video playback controls area (see the illustration below).

The timeline of the embryo development is shown by the vertical black line in the blastomere activity bar chart.

While the time-lapse video is being played, the image acquisition will be temporarily paused as the video would otherwise be interrupted by higher priority tasks (e.g. by the image acquisition or movements of the culture dish holder).

The screenshot displays the EmbryoScope software interface. At the top, there are two tabs: "Video" (selected) and "Live". Below the tabs, the "Slide 1 Well 1" section contains fields for Patient ID (RC 608G), Patient Name (608G), Insemination date (2013-10-10 08:50), Slide Description, and Embryo Description. The main area shows a time-lapse video of an embryo at 22.5 h. To the right of the video is a vertical timeline with a blue dot at 0, ranging from -45 to 45. Below the video is a "Blastomere activity bar" chart showing activity levels over 22 hours. At the bottom, there are "Video playback controls" with buttons for Previous, Play, and Next. Below these are "Back", "Previous Well", and "Next Well" buttons. Arrows point from text labels to these buttons: "Return to the overview screen" to Back, "Go to the previous well in the EmbryoSlide culture dish" to Previous Well, and "Go to the next well in the EmbryoSlide culture dish" to Next Well. To the right of the activity bar, there are "Increase/decrease focal planes" buttons (up and down arrows).

Video tab **Live tab**

Video **Live**

Slide 1 Well 1

Patient ID
RC 608G

Patient Name
608G

Insemination: 2013-10-10 08:50

Slide Description

Embryo Description

Video playback controls

Back Previous Well Next Well

Return to the overview screen Go to the previous well in the EmbryoSlide culture dish Go to the next well in the EmbryoSlide culture dish

Blastomere activity bar

Increase/decrease focal planes

You can pause the video and play it forward or backwards by pressing the corresponding buttons in the video controls area. If images have been recorded from multiple focal planes, you can change the focal plane by pressing the up or down arrows located to the right of the embryo image.

To return to the overview of all wells, press the **Back** button.

6.5 Refocusing embryos

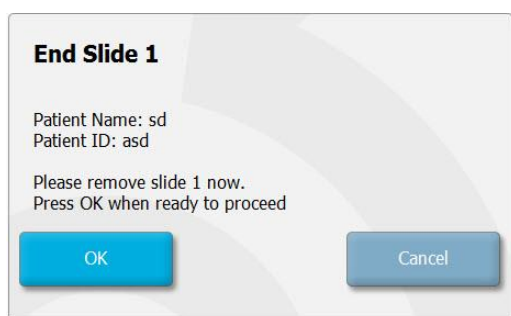
When in **Live** mode, you can refocus the image by manually repositioning the image so that the acquired images are centered on each well:

1. Open the **Live** view.
2. If the embryo is out of focus, press the up or the down arrow to change focal plane (see the illustration above).
3. If you need to, select a new value in the **Increment** field to either increase or decrease the number of micrometers (μm) between each step up or down (used when adjusting the focal plane).
4. When you have found the optimal position and focal plane, press the **New Focus** button. The new focal plane will then be used for all subsequent image acquisitions.
5. When all wells are centered in the field of view and all pictures are in focus, press the **Back** button.
6. Press **Yes** to return to the embryo overview screen and restart the image acquisition.

6.6 Ending an EmbryoSlide culture dish

Follow this procedure to permanently remove an EmbryoSlide culture dish from the EmbryoScope time-lapse incubator:

1. On the home screen, press the EmbryoSlide culture dish you want to remove. The embryo overview screen opens.
2. On the embryo overview screen, press the **End** button. The EmbryoSlide culture dish is now moved to the load area. The lock indicator light in the load door cover will turn green.
3. Remove the EmbryoSlide culture dish and close the load door.
4. Press **OK**.



NOTE

- A specific EmbryoSlide culture dish can also be permanently removed from the **Program Paused** screen (go to the screen for the relevant culture dish and press **Pause**).

7 Routine checks of the EmbryoScope time-lapse incubator

It is recommended to perform scheduled validation checks at least every two weeks to validate the temperature, gas concentrations and cleanliness of the culture dish holder.

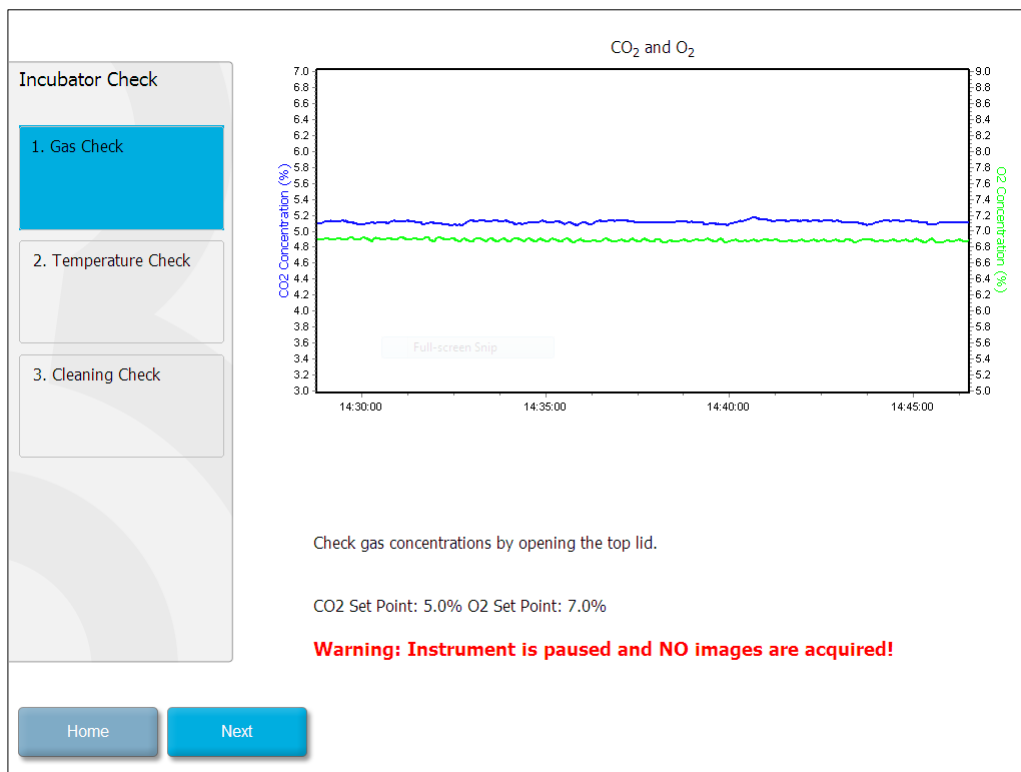
7.1 Starting validation checks

Press **Check...** on the home screen to be guided through the validation procedure. The procedure contains three steps: Gas check, temperature check and cleaning check.

7.2 Gas check

CO₂ and O₂ concentrations are validated by using calibrated external sensors. Open the service lid and the valve on the right to withdraw a sample from the gas sample pipe for analysis. The procedure followed should be in accordance with the specifications of the manufacturer of the external CO₂/O₂ analyzer (see sections 5.5.2 and 5.6.2 for information on how to validate the CO₂ and O₂ concentrations).

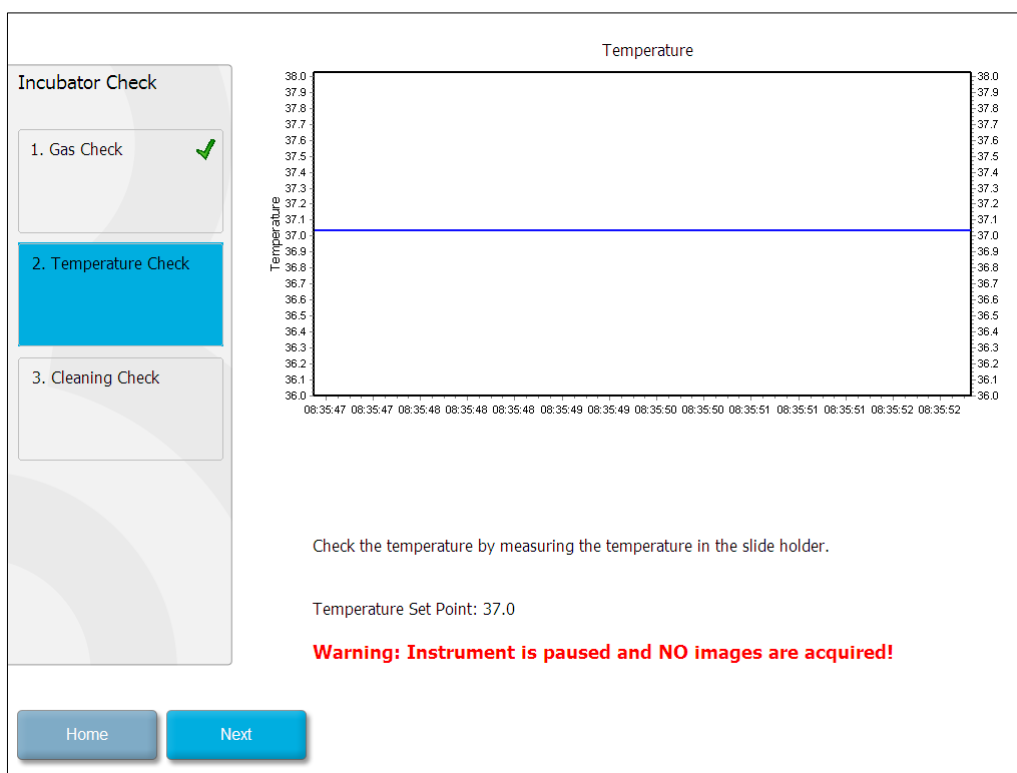




Press **Next** when the validation of the gas concentration is complete.

7.3 Temperature check

To perform a temperature validation check, start by opening the load door of the EmbryoScope time-lapse incubator. The temperature is validated by inserting a calibrated temperature sensor into the culture dish holder. Any certified temperature sensor with proper sensor dimensions may be used in accordance with the manufacturer's guidelines. However, a special socket in the culture dish holder is designed for use with a microsensor connected to a high-precision thermometer (for information on how to validate the temperature, see section 5.4.2).



Press **Next** when the validation of the temperature is complete.

7.4 Cleaning check

To perform a cleaning check, start by opening the load door of EmbryoScope time-lapse incubator. The culture dish holder and embryo chamber must be visually inspected to ensure that no particles or liquid residuals are visible. If the culture dish holder or the embryo chamber need to be cleaned, follow the instructions provided in section 8.

The screenshot shows the 'Incubator Check' screen. On the left, a vertical list of checks is shown: '1. Gas Check' with a green checkmark, '2. Temperature Check' with a green checkmark, and '3. Cleaning Check' which is highlighted with a blue background. To the right of this list, the text 'Check that the slide holder has no visible dust or oil residues.' is displayed. Below this, a section titled 'To remove slide holder for cleaning:' lists seven steps: 1. End all running slides, 2. Close computer by pressing 'End' on Home screen, 3. Power off EmbryoScope (on rear panel), 4. Remove slide holder (see manual), 5. Clean slide holder and re-insert, 6. Start EmbryoScope, and 7. When Scope has started press 'Reset...'. Further down, the word 'Temperature' is shown above a red warning message: 'Warning: Instrument is paused and NO images are acquired!'. At the bottom of the screen, there are two buttons: 'Home' and 'Done'.

Incubator Check

1. Gas Check ✓

2. Temperature Check ✓

3. Cleaning Check

Check that the slide holder has no visible dust or oil residues.

To remove slide holder for cleaning:

1. End all running slides
2. Close computer by pressing "End" on Home screen
3. Power off EmbryoScope (on rear panel)
4. Remove slide holder (see manual)
5. Clean slide holder and re-insert
6. Start EmbryoScope
7. When Scope has started press "Reset..."

Temperature

Warning: Instrument is paused and NO images are acquired!

Home Done

Press **Done** when the cleaning check is complete.

8 Cleaning the EmbryoScope time-lapse incubator

The periodic cleaning procedure is recommended for routine maintenance. The cleaning procedure, combined with the disinfection procedure, is also recommended for event-related concerns such as media spills, visual impurities or other evidence of contamination. It is recommended to clean and disinfect the EmbryoScope time-lapse incubator immediately after any media or oil spills.

8.1 Periodic cleaning of the EmbryoScope time-lapse incubator

NOTE
<ul style="list-style-type: none">• Never clean the EmbryoScope time-lapse incubator with embryos inside.

Wearing gloves and using good handling techniques are important to successful cleaning. Follow this procedure to clean the EmbryoScope time-lapse incubator:

1. Moisten a sterile wipe and clean all internal and external surfaces of the EmbryoScope time-lapse incubator. It is recommended that the unit is cleaned with aqueous 70% isopropyl alcohol.
2. Following cleaning, leave the load door to the embryo chamber open long enough to ensure that all alcohol fumes have dissipated.
3. Wipe the surfaces of the EmbryoScope time-lapse incubator using purified or sterile water.
4. Inspect the EmbryoScope time-lapse incubator. If the time-lapse incubator is visually clean, it is ready for use. If it is not visually clean, go to step 1 and repeat the periodic cleaning procedure.

8.2 Disinfection of the EmbryoScope time-lapse incubator

NOTE
<ul style="list-style-type: none">Disinfection of the EmbryoScope time-lapse incubator involves unmounting the culture dish holder. Always perform a camera reset when the culture dish holder has been unmounted.

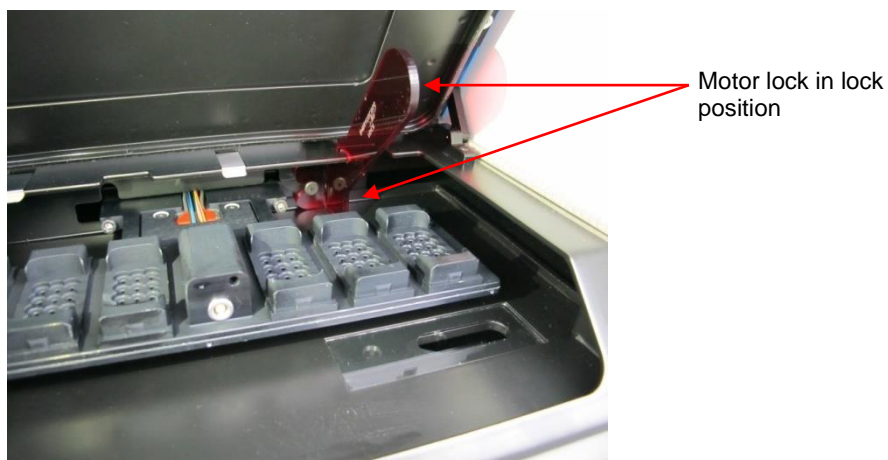
Wearing gloves and using good handling techniques are important to successful cleaning.

Follow the below procedure to disinfect the EmbryoScope time-lapse incubator in case of contamination and/or spillage. The first part of the procedure involves unmounting the culture dish holder:

1. First end all running EmbryoSlide culture dishes by ending each culture dish individually.
2. Check on the home screen that all culture dishes have been ended.
3. Close the PC by pressing **Shutdown** on the home screen.
4. Turn off the EmbryoScope time-lapse incubator by pressing the green main switch found at the rear panel.
5. Open the load door to the embryo chamber.
6. Remove the plate that covers the inaccessible positions of the culture dish holder.



7. Place the motor lock in lock position. The motor lock is the red device that locks the X and Y motors.

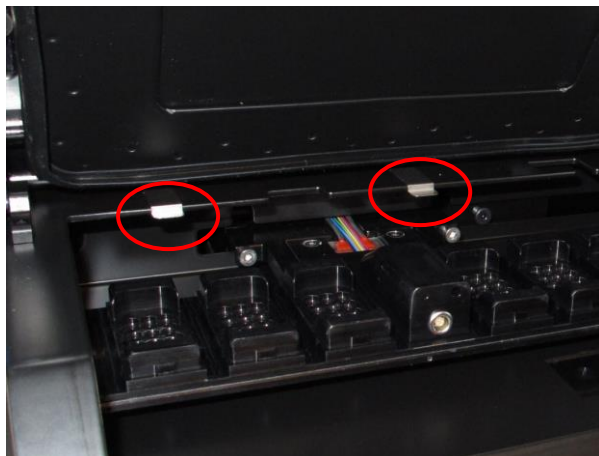


8. Remove the culture dish holder by loosening the two bolts that keep the holder in place. An Allen key can be found together with the emergency procedure beneath the service lid.



9. Pull the culture dish holder gently towards you by using the Allen key.
10. Clean all internal surfaces plus the cover plate and culture dish holder (which has been unmounted from the EmbryoScope time-lapse incubator). Apply EcaFlo Anolyte to sterile wipes and wipe all internal surfaces and the culture dish holder using at least three wipes. Repeat until the wipes are no longer discolored.
11. Change gloves, and after 10 minutes of contact time, spray sterile water over all surfaces and wipe with a sterile polyester wipe. Alternatively, wipe with a polyester wipe dampened with sterile water.
12. Repeat steps 10 and 11 three times.

13. Inspect the EmbryoScope time-lapse incubator. If the time-lapse incubator is visually clean, it is ready for use. If it is not visually clean, go to steps 10 and 11 and repeat the procedure.
14. Gently replace the culture dish holder and mount it with the two bolts. Tighten the bolts; remember to alternate between the two while you tighten.
15. Gently remove the motor lock.
16. Check that both metal clips intended to support the cover plate are firmly attached.



17. Gently replace the cover plate that normally covers the inaccessible positions of the culture dish holder and close the load door.
18. Turn on the EmbryoScope time-lapse incubator by pressing the main switch found at the rear panel.
19. Allow the EmbryoScope time-lapse incubator three hours to equilibrate gas and temperature levels.
20. After three hours, press the **Shutdown** button to close down the software of the EmbryoScope time-lapse incubator.
21. Restart the software and press **Reset** to perform a camera reset.

9 Alarm and information signal system

The EmbryoScope time-lapse incubator integrates an alarm and information signal system that is activated in case an error or another event that needs corrective action has occurred. The alarms and other signals sent by the system can be divided into four main categories and two sub-categories:

- **Warning alarms:** Indicate that the running conditions of the incubator are not as expected. The CO₂ or O₂ concentration in the embryo chamber may e.g. be too low or too high.
- **Incubator malfunction alarm:** Indicates that there is a system error, i.e. a malfunction or power failure of the unit that controls the running conditions of the incubator.
- **Technical alarms:** Indicate that there is a technical error due to a complete power failure of the entire system.
- **Information signals:**
 - **Warning information signals:** Most warning information signals indicate that the operator has failed to perform a required action (such as closing the load door).
 - **Malfunction information signals:** Most malfunction information signals indicate that there is a technical problem with the software or hardware of the EmbryoScope time-lapse incubator. Malfunction information signals indicate technical errors that are less important than a malfunction alarm or a technical alarm.



9.1 Warning alarms

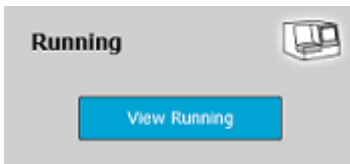
Warning alarms are activated when the temperature or the gas concentration in the incubator deviate from their set points or when the internal gas pressure is too low.

All warning alarms will be recorded and logged in the data files of all EmbryoSlide culture dishes.

9.1.1 Control unit responses to warning alarms

When a warning alarm has been activated, the control units will respond as follows:

Control unit	Response when a warning alarm is activated	Response when the problem is solved
Incubator control panel	<p>A beeping signal will sound. The signal will sound three times followed by a short break after which the signal is repeated. You can pause the audio signal for a duration of three minutes by pressing the pause audio button  once.</p> <p>The yellow LED next to the pause audio button will flash.</p> <p>The display will show which running condition activated the warning alarm (temperature, CO₂ or O₂) as well as the current value of the running condition. If more than one running condition failed at the same time, the associated warning alarms will be displayed in order of priority (see also 9.1.3).</p>	<p>The beeping signal will be switched off (if not already paused by the pause audio button ).</p> <p>The flashing yellow LED will be switched off.</p> <p>The display will show the current temperature.</p>

Control unit	Response when a warning alarm is activated	Response when the problem is solved
Touch screen of the EmbryoScope time-lapse incubator	The button corresponding to the running condition that is currently in error will be colored red (e.g. the CO ₂ button in the lower part of the home screen).	The button that corresponds to the running condition that was previously in error will be colored yellow. When the alarm has been reset, the button changes from yellow to gray.
Connected EmbryoViewer software	<p>The EmbryoViewer software will display a warning alarm for the running condition that is currently in error by coloring the Running area of the navigation panel red.</p>  <p>When you press View Running, you will see which EmbryoScope time-lapse incubator is in error (in case more incubators are connected).</p>	The Running area of the navigation panel will turn yellow when the error is no longer present. When the warning alarm has been reset, the Running area will return to its normal gray color.
External alarm	Activated warning alarms will be communicated to any external alarm system that may be connected to the EmbryoScope time-lapse incubator (see also section 9.5).	No response.

9.1.2 Overview of warning alarms

The following warning alarms may occur:

Temperature is either too high or too low:



Temperature reading is missing:



CO₂ concentration is too high:



CO₂ concentration is too low:



CO₂ inlet pressure is too low:



N₂ inlet pressure is too low:



O₂ concentration is too high:



O₂ concentration is too low:



If an oxygen bottle is accidentally connected to the nitrogen inlet, the O₂ high alarm will be activated when the O₂ concentration surpasses 24%:



9.1.3 Multiple warning alarms

If multiple warning alarms occur at the same time, the display on the control panel will show the warning alarms in order of priority:

The O₂ alarm (activated when the O₂ concentration exceeds 24%) has the highest priority. Therefore, if an O₂ alarm is activated, this will be the only alarm shown in the display until the problem has been solved, even if other warning alarms have occurred as well.

The temperature warning alarm has the second highest priority. This alarm will overrule any other alarm occurring at the same time (except for the O₂ alarm) until the problem has been solved.

If other gas concentration and pressure alarms occur simultaneously, the display will alternate between these alarms. As the individual problems are solved, they will no longer be shown in the display.

9.2 Incubator malfunction alarms

An incubator malfunction alarm will be activated if there is a malfunction or power failure of the unit that controls the running conditions of the EmbryoScope time-lapse incubator.

9.2.1 Control unit responses to an incubator malfunction alarm

When an incubator malfunction alarm has been activated, the control units will respond as follows:

Control unit	Response when an incubator malfunction alarm is activated	Response when the problem is solved
Incubator control panel	<p>A beeping signal will sound for one second followed by a 10-second break. The signal is then repeated.</p> <p>The blue LED in the display will flash.</p> <p>No information about the running conditions (temperature etc.) will appear in the display.</p>	<p>The beeping signal will be switched off.</p> <p>The flashing blue LED will be switched off.</p>
External alarm	The event will be communicated to the external alarm system after two minutes if the EmbryoScope time-lapse incubator cannot be returned to normal operating conditions within this time delay (see section 9.5.1).	No response.
Connected EmbryoViewer software	10 minutes after the external alarm is set off, the touch keys that display the current temperature, CO ₂ concentration and O ₂ concentration inside the incubator will all be colored red.	No response.
PC integrated in the EmbryoScope time-lapse incubator	10 minutes after the external alarm is set off, the touch keys that display the current temperature, CO ₂ concentration and O ₂ concentration inside the incubator will all be colored red.	<p>The touch keys that display the current temperature, CO₂ concentration and O₂ concentration inside the incubator will all be colored yellow.</p> <p>When the alarm has been reset, the color of the touch keys changes from yellow to gray.</p>

9.2.2 Operator response to an incubator malfunction alarm

If an incubator malfunction alarm has been activated, turn off the EmbryoScope time-lapse incubator using the main switch located at the back of the cabinet. Then remove all EmbryoSlide culture dishes by following the emergency procedure described in section 10.

9.3 Technical alarms

A technical alarm will be activated if the power supply to the EmbryoScope time-lapse incubator is completely cut off.

9.3.1 Control unit responses to technical alarms

When a technical alarm has been activated, the control units will respond as follows:

Control unit	Response when a technical alarm is activated	Response when the problem is solved
External alarm	The event will immediately be communicated to the external alarm system without any delay (see section 9.5.1).	No response.

9.3.2 Operator response to technical alarms

If there is a complete power failure, turn off the EmbryoScope time-lapse incubator using the main switch located at the back of the cabinet. Then remove all EmbryoSlide culture dishes by following the emergency procedure described in section 10.

9.4 Information signals

In a number of pre-defined cases, the EmbryoScope time-lapse incubator will display an information signal (a blue LED lamp on the control panel, see also section 5.1). Two types of information signals may be issued: Warning information signals and malfunction information signals (see sections 9.4.1 and 9.4.2 for an in-depth description of each type of information signal).

Warning and malfunction information signals either indicate PC or software errors or function as a reminder for the operator to perform an action, such as closing the load door or responding to a dialog box that is displayed on the touch screen.

PC or software errors may result in a loss of time-lapse images. However, such errors will not affect the running conditions of the EmbryoScope time-lapse incubator as the temperature level and gas concentrations are controlled by an independent unit.

Warning and malfunction information signals cannot be reset unless the condition that caused the signal to be activated is resolved. The condition may possibly be resolved by responding to an error message displayed on the screen or by rebooting the PC.

9.4.1 Malfunction information signals

The EmbryoScope time-lapse incubator will issue a malfunction information signal if:

- The X or Y or focus motor is in error. The motor may e.g. be incorrectly positioned.
- The user has failed to respond to a displayed dialog box for more than 15 minutes (the time delay can be defined by the user).
- An error occurred while initializing the Hall sensor.
- The connection between the camera and the integrated PC has been lost.

9.4.1.1 Control unit responses to malfunction information signals

When a warning information signal is activated, the control units will respond as follows:

Control unit	Response when a malfunction information signal is activated	Response when the problem is solved
Incubator control panel	<p>A beeping signal will sound for one second followed by an 11-second break. The signal is then repeated.</p> <p>A flashing blue LED will be switched on unless the PC is in error.</p>	<p>The beeping signal will be switched off.</p> <p>The flashing blue LED will be switched off.</p>
PC integrated in the EmbryoScope time-lapse incubator	Data about the malfunction information signal will be saved in the database of the EmbryoScope time-lapse incubator.	No response.
Connected EmbryoViewer software	Malfunction information signals will be recorded and logged in the data files for all EmbryoSlide culture dishes unless the signal was activated because the PC was in error.	No response.
External alarm	Activated malfunction information signals will be communicated to the external alarm system (see also section 9.5).	No response.

9.4.2 Warning information signals

The EmbryoScope time-lapse incubator will issue a warning information signal if:

- The integrated PC has been in error for more than five minutes.
- The software integrated in the EmbryoScope time-lapse incubator is not running.
- The connection between the incubator and the integrated PC has been interrupted (possibly because the integrated PC is shut down).
- The load door to the embryo chamber has been left open. The information signal will be activated after 30 seconds.
- The EmbryoScope time-lapse incubator has been paused for more than one hour without reinsertion of an EmbryoSlide culture dish.
- The EmbryoScope time-lapse incubator has been left in **Check** mode for more than half an hour.

9.4.2.1 Control unit responses to warning information signals

When a warning information signal is activated, the control units will respond as follows:

Control unit	Response when a warning information signal is activated	Response when the problem is solved
Incubator control panel	<p>A beeping signal will sound for one second followed by a 10-second break. The signal is then repeated.</p> <p>A flashing blue LED will be switched on unless the PC is in error.</p>	<p>The beeping signal will be switched off.</p> <p>The flashing blue LED will be switched off.</p>
PC integrated in the EmbryoScope time-lapse incubator	<p>Data about the warning information signal will be saved in the database of the EmbryoScope time-lapse incubator.</p> <p>In case the connection between the incubator and the integrated PC has been interrupted, the PC will not receive any information about the running conditions of the incubator. The incubator is, however, still in normal operation as this is monitored by a separate unit. If this situation occurs, the touch keys that display the current temperature, CO₂ concentration and O₂ concentration inside the incubator will all be colored red.</p>	<p>In case the connection between the incubator and the integrated PC has been interrupted, the touch keys that display the current temperature, CO₂ concentration and O₂ concentration inside the incubator will all be colored yellow.</p> <p>When the alarm has been reset, the color of the touch keys changes from yellow to gray.</p>
Connected EmbryoViewer software	Warning information signals will be recorded and logged in the data files for all EmbryoSlide culture dishes unless the signal was activated because the PC was in error.	No response.
External alarm	<p>No response.</p> <p>Activated warning information signals will <i>not</i> be communicated to the external alarm system (see also section 9.5).</p>	Not applicable.

9.5 External alarm system

The external alarm system will only be activated when a number of pre-defined errors occur. Below, you find a list of the errors that will activate the external alarm.

Errors that are not included on this list will not set off the external alarm.

Warning alarms:

- Temperature alarms
- CO₂ concentration alarms
- CO₂ pressure alarms
- O₂ concentration alarms
- N₂ pressure alarms.

Incubator malfunction alarm:

- There is an incubator malfunction or power failure of the unit that controls the running conditions of the EmbryoScope time-lapse incubator.

Technical alarm:

- The power to the entire EmbryoScope time-lapse incubator is completely cut off.

Malfunction information signals:

- Motor errors, e.g. if the motors are incorrectly positioned
- Camera errors
- The user has failed to respond to a displayed dialog box for more than 15 minutes (the time delay can be defined by the user)
- An error occurred while initializing the Hall sensor.

See also sections 9.1.1, 9.2.1, 9.3.1 and 9.4.2.1 for an in-depth description of which alarms and information signals will set off the external alarm.

9.5.1 Delay of external alarms and malfunction information signals

Prior to being sent out externally, the alarms will appear on the control panel of the EmbryoScope time-lapse incubator itself. This will take place two minutes *before* the external alarm is also activated. This e.g. means that temperature warning alarms will be activated immediately on the device itself. Malfunction information signals related to e.g. motor errors will be activated on the device itself after 15 minutes.

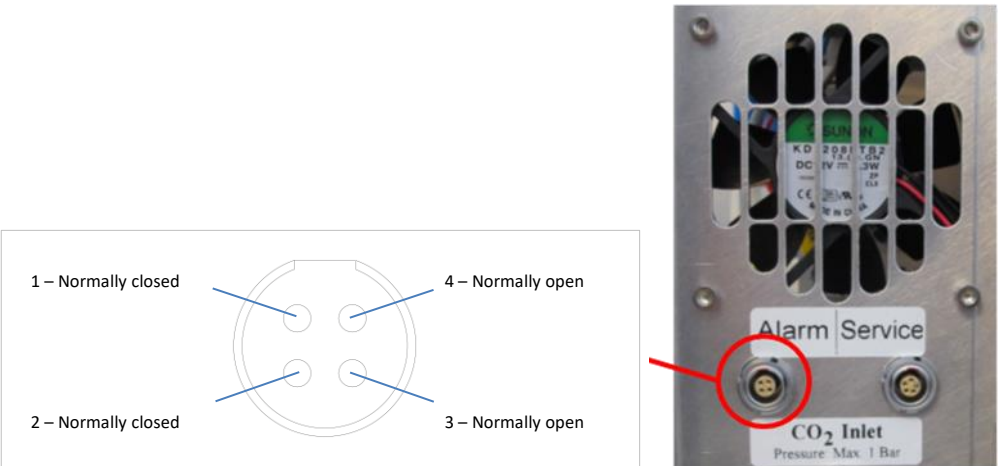
See section 11 for information on when the various alarms and signals are activated on the device itself.

Delays for communicating alarms and signals to the external alarm system		
Warning alarms		Delay (minutes)
1	Temperature alarms	2
2	CO ₂ concentration alarms	5
3	CO ₂ pressure alarms	7
4	O ₂ concentration alarms	7
5	N ₂ pressure alarm	7
Incubator malfunction alarm		Delay (minutes)
6	Malfunction or power failure of the unit that controls the running conditions of the EmbryoScope time-lapse incubator	2
Technical alarm		Delay (minutes)
7	The power to the entire EmbryoScope time-lapse incubator is completely cut off	No delay
Malfunction information signals		Delay (minutes)
(Two minutes will be added to the default delays before the alarm is sent to the external system. The default delays can be configured on the Settings page of the time-lapse incubator.)		
8	No response to displayed dialog box	15 (default)
9	Motor error	15 (default)
10	Camera error	15 (default)
11	Hall sensor error	15 (default)

9.5.2 Connecting the external alarm

The information contained in this section is primarily intended for technical staff members who are tasked with setting up the EmbryoScope time-lapse incubator with an external alarm.

The four-pin alarm plug is labelled *Alarm* and is placed on the rear panel of the EmbryoScope time-lapse incubator:



The EmbryoScope time-lapse incubator supports two types of circuits: Normally closed or normally open. The connected external alarm system should match the chosen circuit.





The colors of the connected electrical wires are different depending on which type of circuit the clinic wants to use:

Normally closed circuit	Normally open circuit
Green and white wires	Brown and yellow wires

9.5.3 Normally open and normally closed circuits

Normally closed circuits are completed when they are in their “normal” state, i.e. when the EmbryoScope time-lapse incubator is in normal operation. When an error condition occurs or when the time-lapse incubator is shut down (e.g. as a result of a power failure), the circuit is broken and the alarm will be activated.

Normally open circuits are completed when they are *not* in their “normal” state, i.e. when an error condition has occurred in the EmbryoScope time-lapse incubator. This means that the alarm will be activated when an error condition occurs and the circuit is closed.

	Normally closed, pins 1 and 2	Normally open, pins 3 and 4
Normal state		
Error		

10 Emergency procedure

The emergency procedure is also found under the service lid.

10.1 Removing EmbryoSlide culture dishes after a power failure

1. Turn on the EmbryoScope time-lapse incubator using the main switch (the green switch at the back, upper left corner).
2. When everything has been initialized and the welcome screen appears, press **Remove Slides**.

10.2 Removing EmbryoSlide culture dishes after a system failure

The safest way to terminate an EmbryoSlide culture dish is described in section 6.6. However, in case of an emergency, a culture dish can be terminated IMMEDIATELY by performing the following actions.

NOTE
<ul style="list-style-type: none">• The emergency procedure may only be used when all other options to safeguard the running EmbryoSlide culture dish have failed.

1. Turn off the EmbryoScope time-lapse incubator on the main switch.

The main switch is the illuminated green switch on the rear side, upper left corner.

2. Find the 2.5 mm and 3 mm Allen keys that are stored together with the emergency procedures beneath the service lid.



3. Disengage the load door lock by pressing the 2.5 mm Allen key into the socket and pressing down the red load door lock indicator.



4. Open the load door to the embryo chamber.



5. Remove the cover plate.



6. If necessary, use a 2.5 mm or 3 mm Allen key to pull the culture dish holder towards the left until it is positioned in the load area from which the EmbryoSlide culture dishes can be removed.



7. To resume using the EmbryoScope time-lapse incubator, reinsert the cover plate, close the load door, turn on the time-lapse incubator and follow the instructions for recalibration and adding EmbryoSlide culture dishes found in sections 5 and 6.3.

11 Technical specifications

Additional information on the specifications is found under the respective sections in this manual.

Incubator:

- Capacity: 6 EmbryoSlide culture dishes containing 12 embryos each, i.e. 72 embryos in total.
- Temperature range: 7°C above ambient temperature (although never lower than 30°C), maximum 45°C. The temperature set point can be adjusted in steps of 0.1°C.
- Temperature accuracy during incubation: +/- 0.1°C.
- CO₂ range: 2-10%. The CO₂ set point can be adjusted in steps of 0.1%.
- CO₂ accuracy: +/- 0.2%.
- O₂ range: 5-20%. The O₂ set point can be adjusted in steps of 0.1%.
- O₂ accuracy: +/- 0.3%.
- Recovery times when the load door is closed after a 30-second load door opening:
 - Temperature, measured in the medium inside the EmbryoSlide culture dish: < 5 minutes
 - CO₂ concentration, measured when the CO₂ concentration set point is 5% and the N₂ regulation is turned off: < 5 minutes
 - CO₂ concentration, measured when the CO₂ and O₂ concentration set points are both 5%: < 5 minutes
 - O₂ concentration, measured when the CO₂ and O₂ concentration set points are both 5%: < 15 minutes.

Alarms and information signals:

- Warning alarms (communicated to the external alarm system):
 - Immediately displayed on the control panel when the temperature deviates by +/- 0.5 from the set point.
 - Displayed on the control panel after 3 minutes when the CO₂ concentration deviates by +/- 1% from the set point.
 - Displayed on the control panel after 2 minutes when the CO₂ pressure is less than 0.2 bar.
 - Displayed on the control panel after 5 minutes when the O₂ concentration deviates by +/- 1% from the set point.
 - Displayed on the control panel after 2 minutes when the N₂ pressure is less than 0.2 bar.

- Incubator malfunction alarm (communicated to the external alarm system):
 - Malfunction or power failure of the unit that controls the running conditions of the EmbryoScope time-lapse incubator.
- Technical alarm (communicated to the external alarm system):
 - The power to the entire EmbryoScope time-lapse incubator is completely cut off.
- Malfunction information signals (by default activated on the EmbryoScope time-lapse incubator 15 minutes after the error has occurred. Also communicated to the external alarm system after an additional two minutes):
 - Motor errors
 - Camera errors
 - No response to displayed dialog box
 - Hall sensor error.
- Warning information signals (*not* communicated to the external alarm system):
 - The integrated PC has been in error for more than five minutes.
 - The software integrated in the EmbryoScope time-lapse incubator is not running.
 - The connection between the incubator and the integrated PC has been interrupted.
 - The load door to the embryo chamber has been left open for more than 30 seconds.
 - The EmbryoScope time-lapse incubator has been paused for more than one hour without reinsertion of an EmbryoSlide culture dish.
 - The EmbryoScope time-lapse incubator has been left in **Check** mode for more than half an hour.

Air flow:

- Recirculation: > 60 l/h (full purification of gas volume every 20 minutes).
- HEPA filter retains 99.97% particles > 0.3 µm.
- Active carbon filter.

Embryo images:

- 1280 x 1024 pixels monochrome CCD camera.
- Leica custom-made, high-quality 20x, 0.40 LWD Hoffman Modulation Contrast objective providing a resolution of 3 pixels per μm .
- Illumination: Single red LED (635 nm, duration < 0.1 seconds per image).
- Total light exposure time: < 50 seconds per day per embryo.
- The images are stored in a resolution of 500 x 500.
- Time between image acquisitions: 10 minutes' cycle time for a maximum of 7 focal planes, 2 minutes' cycle time for a maximum of 1 focal plane.

Other information:

- Power supply: 100-240 VAC.
- Frequency: 50-60 Hz.
- Maximum power consumption: 250 VA.
- Gas requirements: CO_2 and N_2 .
- CO_2 consumption at 5% CO_2 : < 1 l/h without reduced O_2 . With reduced O_2 consumption at 5%: < 2 l/h.
- N_2 consumption at 5% O_2 : < 20 l/h.
- Dimensions (W x D x H): 60 x 56 x 44 cm.
- Weight: 60 kg.
- The IP rating of the incubator is IPX0: Non-protected against ingress of water
- Mains power cable:
 - US and Canada: Maximum 3 meters, HG-SJT 3*18AWG, 125 VAC, 13 A; UL, CSA
 - Outside of US and Canada: Maximum 3 meters, minimum 125 VAC, minimum 10 A.

List of cables and their maximum length:

Name	Category	Type	Maximum length
External alarm	Signal	Shielded	25 meters
AC mains	AC power	Unshielded	3 meters
Ethernet (CAT6)	Telecom	Shielded	30 meters

Isolation of poles:

- Isolation on all poles simultaneously is achieved by either turning off the EmbryoScope time-lapse incubator using the mains switch at the back of the time-lapse incubator or by unplugging the power supply cord from the power supply socket.

Installation:

- Installation and repair of the EmbryoScope time-lapse incubator may only be carried out by a person certified by Vitrolife. Installation instructions are available in the service manual.

Environmental conditions during operation:

- Ambient temperature: 20°C to 30°C.
- Relative humidity: 0% to 85%.
- Operating altitude: < 2,000 m.

Environmental conditions during storage and transportation:

- Ambient temperature: -10°C to +50°C.
- Relative humidity: 30% to 80%.

When received, all shipping boxes should be inspected for signs of damage during transportation. In case the boxes are damaged, please contact Vitrolife immediately for further instructions. Do NOT open the boxes. Leave the EmbryoScope time-lapse incubator in the shipping boxes in a dry and safe place until it can be handled by a person certified by Vitrolife.

Behavior in case EMC immunity test levels are exceeded:

If the incubator is subjected to EMC immunity levels exceeding the levels tested, malfunctions and instabilities may occur, e.g. alarms and screen flickering.

Fuses:

ID	Breaking capacity	Operating speed and current	Temperature	Voltage (AC)	Component
F1	100 A (L)	T2,5 A	N/A	250 V	Incubator
F2	100 A (L)	T1,6 A	N/A	250 V	Motor controller
F3	100 A (L)	T2,5 A	N/A	250 V	Integrated PC
F4	100 A (L)	T1,6 A	N/A	250 V	Touch screen
F6	8 A (L)	10 A	72°C	250 V	Temperature
F7	100 A (L)	T1,6 A	N/A	250 V	Electronics
F230 VAC	35 A (L)	2 x T3,15 A	N/A	250 V	EmbryoScope time-lapse incubator

12 EMC and HF technical review

Medical electrical equipment needs special precautions regarding EMC and must be installed and put into service according to the EMC specifications provided in this section.

WARNING

- The use of accessories, transducers and cables other than those specified, with the exemption of transducers and cables sold by the manufacturer of the system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.
- The EmbryoScope time-lapse incubator should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the incubator should be observed to verify normal operation in the configuration in which it will be used.

12.1 Electromagnetic emissions

The below table contains the applicable information required for CISPR11 systems:

Guidance and manufacturer's declaration – electromagnetic emissions The EmbryoScope time-lapse incubator is intended for use in the home healthcare environment specified below. The customer or the user of the EmbryoScope time-lapse incubator should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
Conducted emission EN/CISPR 11:2010	Group 1	The EmbryoScope time-lapse incubator uses RF energy only for its internal functions. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment. The risk of causing undesirable effects on the operator or other personnel close to the incubator is negligible. The EmbryoScope time-lapse incubator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emission EN/CISPR 11:2010	Class B	
Harmonic emission IEC 61000-3-2:2009	Class A	
Voltage fluctuation (flicker emission) IEC 61000-3-3:2013	Complies	

12.2 Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity The EmbryoScope time-lapse incubator is intended for use in the home healthcare environment specified below. The customer or the user of the EmbryoScope time-lapse incubator should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 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 61000-4-4:2012	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5:2005	± 0.5 kV, ± 1 kV line-to-line ± 0.5 kV, ± 1 kV, ± 2 kV line-to-ground	± 0.5 kV, ± 1 kV line-to-line ± 0.5 kV, ± 1 kV, ± 2 kV line-to-ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11:2004	EUT: Reduction of input voltage to 0% for 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Result: PASS: No change in operation. The system remained safe.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EmbryoScope time-lapse incubator requires continued operation during mains power interruptions, it is recommended that the incubator be powered from an uninterruptible power supply or battery. EUT remained safe during the test.
	Reduction of input voltage to 0% for 1 cycle @ 0°	PASS: No change in operation. The system remained safe.	
	Reduction of input voltage to 70% for 30 cycles @ 0°	PASS: No change in operation. The system remained safe.	
	Reduction of input voltage to 0% for 300 cycles	PASS: The system is allowed to turn off as long as it establishes normal operation after the test.	
Power frequency (50/60 Hz) magnetic fields IEC 61000-4-8:2009	30 A/m	30 A/m PASS: No change in operation. The system remained safe.	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

The two tables below contain the applicable information required for a system other than those specified for use only in a shielded location and for systems that are not life-supporting.

Guidance and manufacturer’s declaration – electromagnetic immunity				
The EmbryoScope time-lapse incubator is intended for use in the home healthcare environment specified below. The customer or the user of the EmbryoScope time-lapse incubator should assure that it is used in such an environment.				
Immunity test		IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6:2013		3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 150 kHz to 80 MHz	EUT remained safe during the test in normal operational mode and in alarm mode. It is recommended that portable and mobile RF communications equipment is used no closer to any part of the EmbryoScope time-lapse incubator, including cables, than 0.3 meters, which corresponds to the distance of the test level applied. Otherwise, degradation of the performance of the EmbryoScope time-lapse incubator could result.
Radiated RF IEC 61000-4-3:2006 + A1:2007 + A2:2010		10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	
Radiated RF IEC 61000-4-3:2006 + A1:2007 + A2:2010 – Proximity fields from RF wireless communications equipment	TETRA 400	385 MHz, PM, 18 Hz, 1.8 W, 27 V/m	385 MHz, PM 18 Hz, 1.8 W, 27 V/m	
	GMRS 460 FRS 460	450 MHz, FM, ± 5 kHz dev., 1 kHz sine, 2 W, 28 V/m	450 MHz, FM, ± 5 kHz dev., 1 kHz sine, 2 W, 28 V/m	
	LTE Band 13 LTE Band 17	710/745/780 MHz, PM, 217 Hz, 0.2 W, 9 V/m	710/745/780 MHz, PM, 217 Hz, 0.2 W, 9 V/m	
	GSM 800 GSM 900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	810/870/930 MHz, PM, 18 Hz, 2 W, 28 V/m	810/870/930 MHz, PM, 18 Hz, 2 W, 28 V/m	
	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1 LTE Band 3 LTE Band 4 LTE Band 25	1720/1845/1970 MHz, PM, 217 Hz, 2 W, 28 V/m	1720/1845/1970 MHz, PM, 217 Hz, 2 W, 28 V/m	

Guidance and manufacturer's declaration – electromagnetic immunity

The EmbryoScope time-lapse incubator is intended for use in the home healthcare environment specified below. The customer or the user of the EmbryoScope time-lapse incubator should assure that it is used in such an environment.

Immunity test		IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
	Bluetooth WLAN 802.11 b WLAN 802.11 g WLAN 802.11 n RFID 2450 LTE Band 7	2450 MHz, PM, 217 Hz, 2 W, 28 V/m	2450 MHz, PM, 217 Hz, 2 W, 28 V/m	
	WLAN 802.11 a WLAN 802.11 n	5240/5500/5785 MHz, PM, 217 Hz, 0.2 W, 9 V/m	5240/5500/5785 MHz, PM, 217 Hz, 0.2 W, 9 V/m	

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.

- 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 transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EmbryoScope time-lapse incubator is used exceeds the applicable RF compliance level above, the EmbryoScope time-lapse incubator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the incubator.

Recommended separation distances between portable and mobile RF communications equipment and the EmbryoScope time-lapse incubator

The EmbryoScope time-lapse incubator is intended for use in a home healthcare environment in which radiated RF disturbances are controlled. The customer or the user of the EmbryoScope time-lapse incubator can help prevent electromagnetic interference by maintaining a minimum distance between portable RF communications equipment (transmitters) and the EmbryoScope time-lapse system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power (P) of transmitter [W]	Minimum separation distance (d) according to frequency of transmitter [m]	
	@ Immunity test level (E) 3 V/m, 0.15-80 MHz	@ Immunity test (E) 10 V/m, 80-2700 MHz
0.06	0.49	0.15
0.12	0.69	0.21
0.25	1.00	0.30
0.5	1.41	0.42
1	2.00	0.60
2	2.83	0.85

Calculation: $d = \frac{6 * \sqrt{P}}{E}$

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

At 80 MHz, the separation distance for the higher frequency applies.

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

13 Accessories and materials

The following equipment and materials are needed to run the EmbryoScope time-lapse incubator:

- EmbryoSlide culture dishes (refer to the user manual for the EmbryoSlide culture dishes)
- EmbryoViewer software
- Motor lock (see section 8.2)
- A set of Allen keys, 2.5 mm and 3 mm, respectively (found under the service lid)
- Aqueous 70% isopropyl alcohol (see section 8.1)
- Access to CO₂ and N₂ (clinic-specific)
- For calibration: High-precision thermometer connected to a probe (see section 5.4.2) and gas analyzer (see section 5.5.2, 5.5.3 and 5.6.3).

The thermometer and gas analyzer used when calibrating the incubator should be as least as accurate as the values displayed on the incubator itself or better, i.e.:

- Recommended accuracy for high-precision thermometer in the range between 36°C and 39°C: +/- 0.2°C
- Recommended accuracy for CO₂ gas analyzer in the range between 3% and 8%: +/- 0.3%
- Recommended accuracy for O₂ gas analyzer in the range between 4% and 8%: +/- 0.5%.

14 Planned service and maintenance

A person certified by Vitrolife will inspect and replace all of the following items in accordance with the intervals specified in the below table.

Replaceable item	Description	Service interval (years)	Replaced by
VOC HEPA filter	VOC HEPA filter	0.5	Certified service personnel
O ₂ sensor	1 x sensor placed on the mixing chamber	0.5	Certified service personnel
UV light	Internal UV light placed in the mixing chamber	0.5* 1**	Certified service personnel
Internal blower	Primary fan	5	Certified service personnel
External HEPA filters	External HEPA filters on the gas inlet side	3	Certified service personnel
Internal mini HEPA filters	Internal HEPA filters placed just inside the gas entrance	5	Certified service personnel
12 V power supply unit	Internal 12 V power supply unit	5.5	Certified service personnel








The UV light service interval differs between ballasts, which is indicated by * (UV light ballast, 220 V) and ** (HF-Matchbox Blue 109 LH-PLS).









To ensure error-free operation, regular service checks are mandatory. We recommend that the service check be performed by a person certified by Vitrolife.

The default frequency for scheduled periodic service checks is six months.





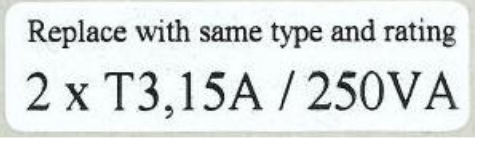
15 Symbols and labels

15.1 Product information labels

Label	Description	Note
Vitrolife A/S Jens Juuls Vej 20, 8260 Viby J Denmark +45 7221 7900	Manufacturer information	Placed at the upper end of the panel. See section 17.
	Model	See the front page of the user manual.
	Model reference number	-
	Type of power supply	See sections 2.1 and 11.
	Protection against electric shock – type B	See section 1.
	Declaration by the manufacturer that the device meets all of the applicable requirements in the Medical Device Regulation (EU) 2017/745	-
	ETL approval	-
	Medical device	-

Label	Description	Note
	Unique device identifier	-
	Manufacturer name and logo	See section 17.
	Year and month of production	YYYY-MM
	Country of origin	-
	Serial number	Model-version-production number
	Caution when discarded	See section 16.
	Humidity limitation	%
	Atmospheric pressure limitation	kPa

15.2 Connection labels

Label	Description	Note
	Direction of flow through the HEPA filter	Found under the service lid at the top of the EmbryoScope time-lapse incubator. See section 2.
Alarm	External alarm output socket label	See section 4.
Service	Service readout socket label	Only to be used by a person certified by Vitrolife. See section 4.
	CO ₂ connection inlet information	See section 4.
	N ₂ connection inlet information	See section 4.
	Ethernet connection socket label	See section 4.
	Fuse replacement information	See sections 4 and 11.

16 Disposal of waste

In order to minimize the waste of electrical and electronic equipment, waste must be disposed in accordance with the Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) as amended by Directive (EU) 2018/849. This includes: PCBs (lead-free HASL), switches, PC batteries, printed circuit boards and external electrical cables. All components are in accordance with the RoHS 2 Directive 2011/65/EU, which states that new electrical and electronic components do not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers.

It should, however, be noted that the oxygen sensor and UV lamp (which may or may not be active in your specific product) contain toxic compounds, irrespective of their physical condition. This is in accordance with the provisions of the RoHS Directive mentioned above.

Taking into account the toxic content, the oxygen sensor and UV lamp should be disposed of according to local waste management requirements and environmental legislation. They should not be burned since they may evolve toxic fumes.

17 Contact information

Urgently need help? Call our service hotline for support:

+45 7023 0500

(available 24 hours a day, 7 days a week)

E-mail support: support.embryoscope@vitrolife.com

(response within two working days)



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