

User Manual



MIRI[®] TL Viewer Software

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Rx only

CE
0123



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Copyright Information

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Esco reserves the right to make periodic minor design changes without obligation to notify any person or entity of such change.

Sentinel™ are registered trademark of Esco.

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Only to be used by a trained and qualified professional. The device is sold under exemption 21 CFR 801 Subpart D.

"Material in this manual is provided for informational purposes only. The contents and the product described in this manual (including any appendix, addendum, attachment or inclusion), are subject to change without notice. Esco makes no representations or warranties as to the accuracy of the information contained in this manual. In no event shall Esco be held liable for any damages, direct or consequential, arising out of or related to the use of this manual."

Unpacking and Inspection

Follow standard receiving practices upon receipt of the medical device. Check the shipping carton for damage. If the damage is found, stop unpacking the medical device. Notify the freight carrier and ask for an agent to be present while the medical device is unpacked. There are no special unpacking instructions, but be careful not to damage the medical device when unpacking it. Inspect the medical device for physical damage such as bent or broken parts, dents, or scratches.

Claims

Our routine method of shipment is via common carrier. If physical damage is found, upon delivery, retain all packing materials in their original condition and immediately contact the carrier to file a claim.

If the device is delivered in good physical condition but does not operate within specifications, or if there are any other problems not caused by shipping damage, please contact your local sales representative or Esco Medical Technologies, UAB immediately.

Standard Terms and Conditions

Refunds & Credits

Please note only serialized products (products labeled with a distinct serial number) and accessories are eligible for a partial refund and/or credit. Non-serialized parts and accessory items (cables, carrying cases, auxiliary modules, etc.) are not eligible for return or refund. In order to receive a partial refund/credit, the product must not have been damaged. It must be returned complete (meaning all manuals, cables, accessories, etc.) within 30 days of original purchase, in “as new” and resalable condition. The *Return Procedure* must be followed.

Return Procedure

Every product returned for refund/credit must be accompanied by a Return Material Authorization (RMA) number obtained from Esco Medical Technologies, UAB Customer Service. All items being returned must be sent *prepaid* (freight, duty, brokerage and taxes) to our factory location.

Restocking Charges

Products returned within 30 days of original purchase are subject to a minimum restocking fee of 20% of the list price. Additional charges for damage and/or missing parts and accessories will be applied to all returns. Products that are not in “as new” and resalable condition are not eligible for credit return and will be returned to the customer at their own expense.

Certification

This device has been thoroughly tested/inspected and found to meet Esco Medical Technologies, UAB manufacturing specifications when shipped from the factory. Calibration measurements and testing are traceable and done according to Esco Medical Technologies, UAB ISO certification.

Warranty and Product Support

Esco Medical Technologies, UAB warrants this device to be free from defects in materials and workmanship under regular use and service for two (2) years from the original purchase date, provided the device is calibrated and maintained following this manual. During the warranty period, Esco Medical Technologies, UAB will, at our option, either repair or replace a product that proves to be defective at no charge, provided you return the product (shipping, duty, brokerage and taxes prepaid) to Esco Medical Technologies, UAB. Any transportation charges incurred are the purchaser's responsibility and are not included within this warranty. This warranty extends only to the original purchaser. It does not cover damage from abuse, neglect, accident or misuse, or as the result of service or modification by parties other than Esco Medical Technologies, UAB.

IN NO EVENT SHALL ESCO MEDICAL TECHNOLOGIES, UAB. BE LIABLE FOR CONSEQUENTIAL DAMAGES.

No warranty shall apply when any of the following causes damage:

- Power failure, surges, or spikes.
- Damage in transit or when moving the device.
- An improper power supply such as low voltage, incorrect voltage, defective wiring or inadequate fuses.
- Accident, alteration, abuse or misuse of the device.
- Fire, water damage, theft, war, riot, hostility, acts of God such as hurricanes, floods, etc.

Only CultureCoin® products (those items bearing a distinct serial number tag) and their accessory items are covered under this warranty.

PHYSICAL DAMAGE CAUSED BY MISUSE OR PHYSICAL ABUSE IS NOT COVERED UNDER THE WARRANTY. Items such as cables and non-serialized modules are not covered under this warranty.

This warranty gives you specific legal rights and you may have other rights, which vary from province to province, state to state, or country to country. This warranty is limited to repairing the device per Esco Medical Technologies, UAB specifications.

When you return the medical device to Esco Medical Technologies, UAB, for service, repair or calibration, we recommend shipment using the original shipping foam and container.

If the original packing materials are not available, we recommend the following guide for repackaging:

- Use a double-walled carton of sufficient strength for the weight being shipped.
- Use heavy paper or cardboard to protect all device surfaces. Use non-abrasive material around all projecting parts.

- Use at least four inches of tightly packed, industrial-approved, shock-absorbent material all around the device.

Esco Medical Technologies, UAB, will not be responsible for lost shipments or medical devices received in damaged condition due to improper packaging or handling. All warranty claim shipments must be made on a prepaid basis (freight, duty, brokerage, and taxes). No returns will be accepted without a Return Materials Authorization ("RMA") number. Please contact Esco Medical Technologies, UAB to obtain an RMA number and receive help with shipping/customs documentation.

Re-calibration of the medical devices, which have a recommended annual calibration frequency, is not covered under warranty.

Warranty Disclaimer

If your medical device is serviced and/or calibrated by someone other than Esco Medical Technologies, UAB, and their representatives, please be advised that the original warranty covering your product becomes void when the tamper-resistant Quality Seal is removed or broken without proper factory authorization.

In all cases, breaking the tamper-resistant Quality Seal should be avoided at all cost, as this seal is key to your original medical device warranty. In an event where the seal must be broken to gain internal access to the medical device, you must first contact Esco Medical Technologies, UAB.

You will be required to provide us with the serial number for your medical device, as well as a valid reason for breaking the Quality Seal. You should break this seal only after you have received factory authorization. Do not break the Quality Seal before you have contacted us! Following these steps will help ensure that you will retain the original warranty on your medical device without interruption.

WARNING

Unauthorized user modifications or applications beyond the published specifications may result in an electrical shock hazard or improper operation. Esco Medical Technologies, UAB will not be responsible for any injury sustained due to unauthorized equipment modifications.

ESCO MEDICAL DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

THIS PRODUCT CONTAINS NO USER-SERVICEABLE COMPONENTS.

UNAUTHORIZED REMOVAL OF THE MEDICAL DEVICE COVER SHALL VOID THIS AND ALL OTHER EXPRESSED OR IMPLIED WARRANTIES.

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1 How to use this manual

The manual is designed to be read by sections and not ideally from cover to cover. It means that if the manual is read from start to finish, there will be some repetition and overlap.

 **Digital versions of the English user manual and all translated versions are available on our website, www.esco-medical.com.**

To locate this user manual, simply follow these steps:

1. Click on the “Products” tab in the navigation menu.
2. Scroll down and select “MIRI® Time-Lapse incubator”.
3. Continue scrolling further down to find the “Literature & Resources” section.
4. Click on the “Information for Users” tab.

2 Safety warning

- Anyone working with, on or around this equipment should read this manual. Failure to read, understand, and follow the instructions given in this documentation may damage the unit, injure operating personnel, and/or poor equipment performance.
- Any internal adjustment, modification or maintenance to this equipment must be undertaken by qualified service personnel.
- In this manual, important safety-related points will be marked with the following symbols:



NOTE

It is used to direct attention to a specific item.



WARNING

Use caution.

3 Intended purpose/use

Esco Medical MIRI® TL family’s multiroom IVF incubators are intended to provide an environment with controlled temperature, CO₂ and other gases for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. The device use is limited up to six days (199 hours), covering the time from post-fertilization to day 6 of the development.

4 About the product

The Esco Medical MIRI® TL family's multiroom IVF incubator are a CO₂/O₂ incubators with time-lapse capability. In the MIRI® TL6 it is possible to incubate up to 84 embryos, whereas in the MIRI® TL12 – up to 168 embryos can be incubated simultaneously. The multiroom IVF incubators can generate time-lapse images and provide them to identify development quality and stages.

The only dish used with MIRI® TL6 and MIRI® TL12 multiroom IVF incubators is the CultureCoin®.

Direct warming of the dishes in the chambers gives superior temperature conditions in comparison to conventional multiroom IVF incubators.

The temperature in the chamber will remain stable up to 1 °C (even when a lid is open for 10s) and will recover within 1 min after the lid is closed.*

The Esco Medical MIRI® TL6 multiroom IVF incubator has 6 completely separate culture heat chambers, whereas MIRI® TL12 has 12 chambers. Each chamber has its own heated lid and a room for one CultureCoin® dish.

To ensure maximum performance, the system of MIRI® TL6 multiroom IVF incubator has 12 completely separate PID temperature controllers, whereas MIRI® TL12 has 24. They control and regulate temperature in culture chambers and lids. Chambers do not affect each other's temperatures in any way. The top and the bottom of each chamber is separated with a PET layer so that the lid temperature would not affect the bottom. For validation purposes, each chamber has a PT-1000 sensor built in. The circuitry is separated from the device's electronics so it remains a truly separate validation system.

The multiroom IVF incubator has to be supplied with 100% CO₂ and 100% N₂ in order to be able to control the CO₂ and O₂ gas concentrations in the culture chambers.

A dual beam infrared CO₂ sensor with extremely low drift rates controls the CO₂ concentration. A chemical medical grade oxygen sensor controls the concentration of O₂.

CO₂ recovery time takes an average of 3 minutes after the lid is opened for up to 10 seconds.* To validate gas concentration, the MIRI® TL6 multiroom IVF incubator is fitted with 6 gas sample ports that allow the user to sample gas from the individual chamber, whereas MIRI® TL12 has 12.

* Based on internal testing. Performance may vary depending on various factors and environmental conditions.

The multiroom IVF incubator features a recirculated gas system where gas is continuously put into the chamber and taken out at the same rate. Gas is cleaned via 254 nm UVC light with direct gas contact between the bulb and gas, then through a VOC/HEPA filter. The UVC light has filters that inhibit any 185 nm radiation that would produce dangerous ozone. The VOC/HEPA filter is located under the UVC light.

Complete gas repletion in the system takes less than 5 min.

The total gas consumption is very low. Less than 2 l/h CO₂ and 5 l/h N₂ in use.

For safety reasons the multiroom IVF incubator has a gas control system that consists of: pressure regulator (preventing dangerous gas pressure problems), flow PCB (actual consumption can be accumulated), gas pressure sensors (then user knows that the pressure and variation can be logged to avoid dangerous conditions), gas filters (to avoid valve problems).

The CultureCoin® dish location in a chamber is easy to reach and locate because of the chamber numbering and the ability to write on the white lid with a pen.

The multiroom IVF incubator has been primarily developed and designed for incubation of gametes and embryos with an overlay of either Paraffin or mineral oil.

The upright LED display is large, clear and easy to read from a distance. The user can tell if the parameters are correct without going near the device.

The software is running on the built-in touchscreen. PC controls a microscopy system that can generate an image every 5 min. When compiled, these images can be viewed as a time-lapse movie.

The Software contains logging functions for a long-term data logging and storage.

The user can plug any standard BNC pH probe to the device and measure the pH in the samples at will.

MIRI® TL family's multiroom IVF incubators are stationary devices. The term refers to equipment that, once installed and placed into service, is not intended to be moved from one place to another.

Only individuals with formal education in healthcare or medical discipline may work with Esco Medical MIRI® TL family's multiroom IVF incubators.

Esco Medical MIRI® TL family's multiroom IVF incubators are used for in vitro fertilization (IVF) patients. Patients are women in their reproductive years who have fertility health issues. The intended target group indication is IVF treatment. There are no intended target group contraindications.

The device is manufactured under a full EU certified 13485 ISO quality management system.

This product fulfils the requirements of EN60601-1 3rd edition standards as a Class I type B equivalent device suited for continuous operation. It also conforms to the requirements of the Regulation (EU) 2017/745 concerning medical devices and is classified as a Class IIa device under rule II.

Personal Protective Equipment (89/686/EEC) and Machine Directive (2006/42/EC) is not applicable for the MIRI® TL family's multiroom IVF incubators. Also, the MIRI® TL family's multiroom IVF incubators does not contains or incorporates: a medical substance, including a human blood or plasma derivate; tissues or cells, or their derivatives, of human origin; or tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No. 722/2012.

5 About the Viewer Software

The MIRI® TL family's multiroom IVF incubators Viewer software is an information-providing tool that can help the MIRI® TL multiroom IVF incubator users process the data generated by the MIRI® TL6 and MIRI® TL12 multiroom IVF incubators. The software contains a complete patient database. In the database, various details about the patient and treatment can be entered if the user choses so.

The software can also be used without entering any other information other than the patient's name. The software will assign a unique identifier to each patient so they cannot be mistaken. With the unique identifier and the generated timelapse, the software allows for annotating the user's development and a quick graphical comparison tool that allows for comparison embryos. The software also functions as a video player that plays the timelapse video.

The Software will also show incubator status and alarm conditions, but the user alerting and interaction functions are all contained on the device itself.

The current MIRI® TL Viewer software version is 1.22.2.0.

6 Installing the software

The software is pre-installed on the AIO computer provided with the MIRI® TL incubator. The MIRI® TL Viewer software is non-redistributable.

6.1 Updating the software

The software installed on your MIRI® TL6 and MIRI® TL12 multiroom IVF incubator as well as the MIRI® TL Viewer All-in-One computer, or the optional MIRI® TL extended configuration package mini-computer is upgradable. Whenever an important update is available, it will be provided to our distributors around the world – they will ensure that your incubator runs with the newest available software. A service technician can do this during a scheduled annual service

7 Running the Viewer

7.1 Start-up

There is a “MIRI® TL Viewer” start icon on the desktop.



Figure 7.1 “MIRI® TL Viewer” icon on the desktop

Double-clicking on the icon will start the MIRI® TL Viewer application and display it on the main screen.

7.2 Main view

The main view shows 4 buttons:

- Timelapses (a list of the generated Timelapses).
- Patients (the patient’s database).
- Incubators (MIRI® TL6 and MIRI® TL12 multiroom IVF incubators connected to the Viewer).
- Settings (a module that allows the user to customize the parameters, annotation and ideal times).

All interaction with the software is intuitive and straightforward. Navigation between the menus is done by pressing the relevant colored icons or the back arrow in the top left corner.

In the lower left corner of the main MIRI® TL family's multiroom IVF incubators Viewer screen, storage information is also provided to the user.

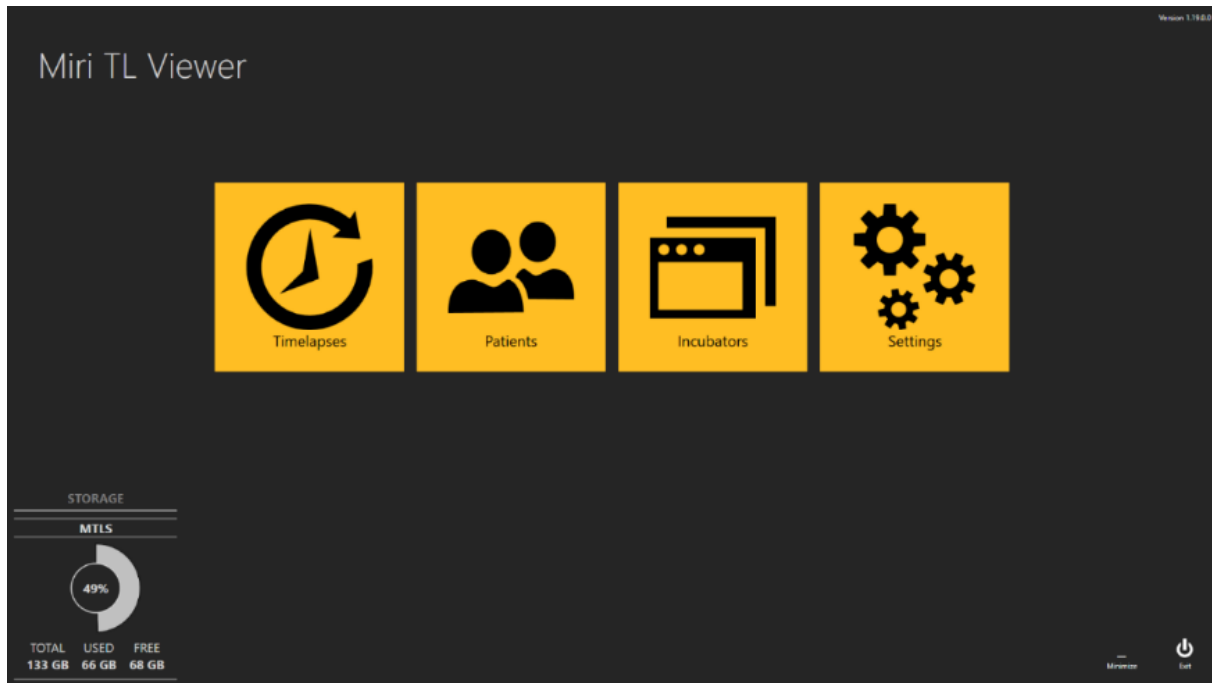
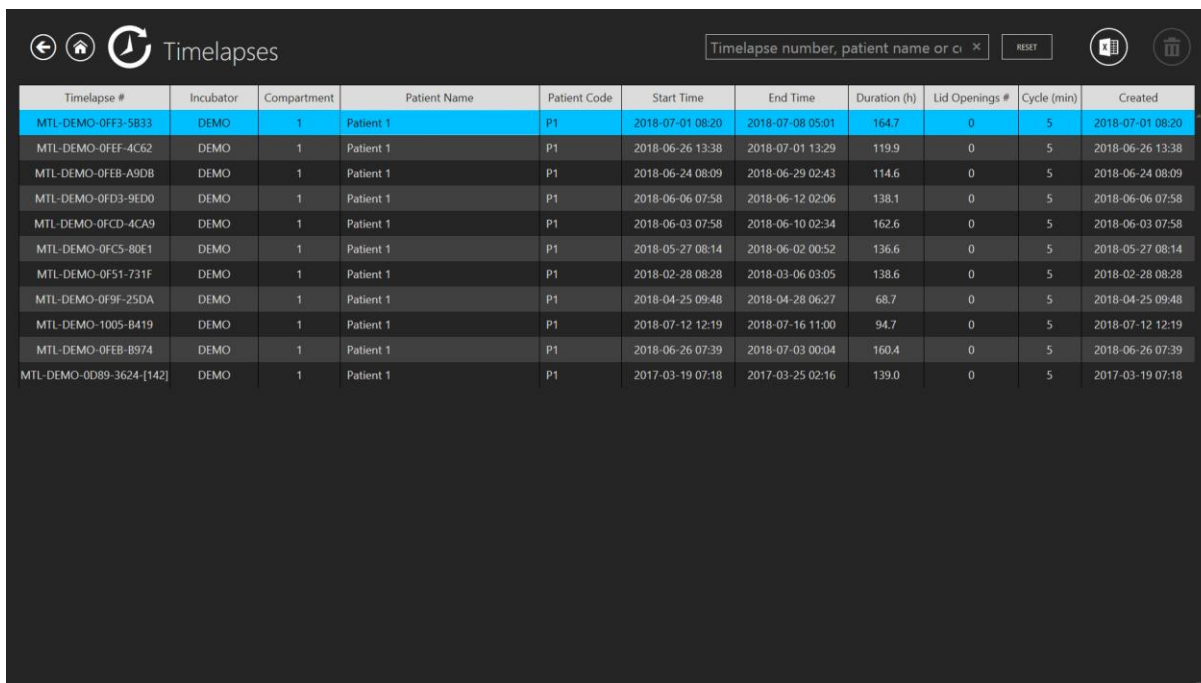


Figure 7.2 MIRI® TL6 and MIRI® TL12 multiroom IVF incubators Viewer main screen

7.3 Timelapses

7.3.1 Timelapse list

Pressing the “Timelapses” button changes the view to the list of the timelapses generated on the connected MIRI® TL family's multiroom IVF incubators. If more than one MIRI® TL6 or MIRI® TL12 multiroom IVF incubators are connected to the extended configuration package, the list will consist of data from all these devices.



Timelapse #	Incubator	Compartment	Patient Name	Patient Code	Start Time	End Time	Duration (h)	Lid Openings #	Cycle (min)	Created
MTL-DEMO-0FF3-5B33	DEMO	1	Patient 1	P1	2018-07-01 08:20	2018-07-08 05:01	164.7	0	5	2018-07-01 08:20
MTL-DEMO-0FEF-4C62	DEMO	1	Patient 1	P1	2018-06-26 13:38	2018-07-01 13:29	119.9	0	5	2018-06-26 13:38
MTL-DEMO-0FEB-A9DB	DEMO	1	Patient 1	P1	2018-06-24 08:09	2018-06-29 02:43	114.6	0	5	2018-06-24 08:09
MTL-DEMO-0FD3-9ED0	DEMO	1	Patient 1	P1	2018-06-06 07:58	2018-06-12 02:06	138.1	0	5	2018-06-06 07:58
MTL-DEMO-0FCD-4CA9	DEMO	1	Patient 1	P1	2018-06-03 07:58	2018-06-10 02:34	162.6	0	5	2018-06-03 07:58
MTL-DEMO-0FC5-80E1	DEMO	1	Patient 1	P1	2018-05-27 08:14	2018-06-02 00:52	136.6	0	5	2018-05-27 08:14
MTL-DEMO-0F51-731F	DEMO	1	Patient 1	P1	2018-02-28 08:28	2018-03-06 03:05	138.6	0	5	2018-02-28 08:28
MTL-DEMO-0F9F-25DA	DEMO	1	Patient 1	P1	2018-04-25 09:48	2018-04-28 06:27	68.7	0	5	2018-04-25 09:48
MTL-DEMO-1005-B419	DEMO	1	Patient 1	P1	2018-07-12 12:19	2018-07-16 11:00	94.7	0	5	2018-07-12 12:19
MTL-DEMO-0FEB-B974	DEMO	1	Patient 1	P1	2018-06-26 07:39	2018-07-03 00:04	160.4	0	5	2018-06-26 07:39
MTL-DEMO-0D89-3624 [142]	DEMO	1	Patient 1	P1	2017-03-19 07:18	2017-03-25 02:16	139.0	0	5	2017-03-19 07:18

Figure 7.3 List of performed timelapses

A multiroom IVF incubator **filter function** is in the top left corner of the main display, where the user can narrow down the timelapse search by selecting the specific incubator. Also, the user can also filter the timelapses by selecting the desired timelapse state: “All”, “Active” or “Finished”.



Figure 7.4 Filter function options

There is a **search function** in the top right corner, where the timelapse number, incubator, patient name or patient code can be entered to perform the search.

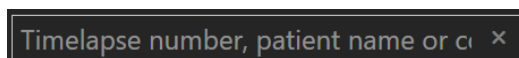


Figure 7.5 Search function

By default, the view will list all timelapses arranged according to the treatment number (a counter that counts from the oldest to the newest timelapse and always adds the new timelapse at the top of the list).

The “Reset” button will reset all selected filters.

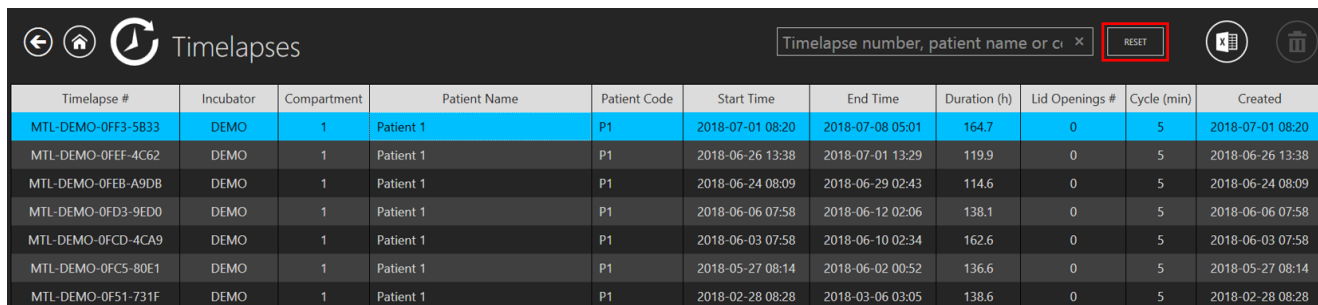


Figure 7.6 “Reset” button

By pressing on a “Report” button in the top right corner of the main MIRI® TL family’s multiroom IVF incubators Viewer’s menu, the user can generate a timelapse annotation file, which will also consist of linked score model results.

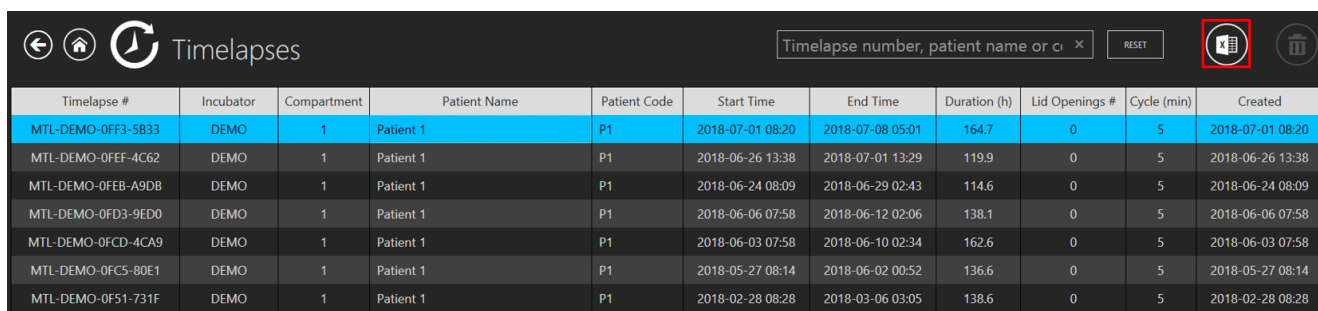


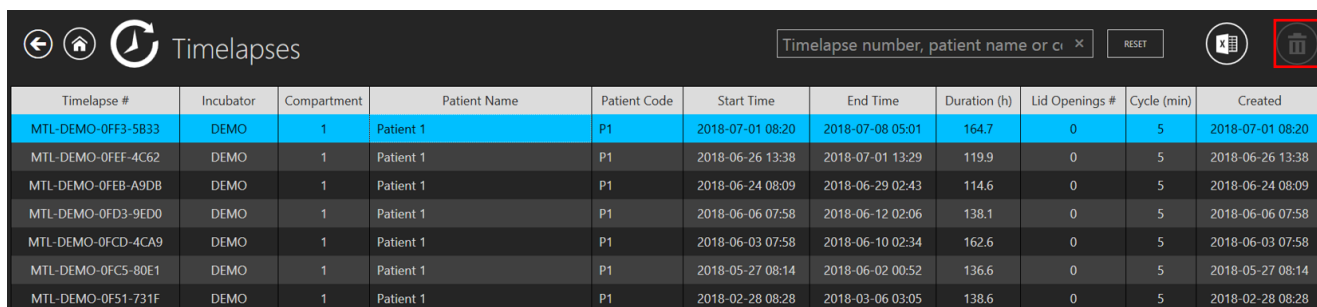
Figure 7.7 “Report” button

In the exported file, the embryo score model results are listed in the last columns of the excel file.

	AV	AW
Models		
	Hierarchical test model	Weighted test model
	N/A	N/A
	N/A	N/A
	N/A	N/A
	N/A	N/A
	Acceptable	6.334
	N/A	N/A
	N/A	N/A
	N/A	N/A

Figure 7.8 Score models location in the exported excel file

The “Delete” button will delete the selected timelapse. The user can delete the timelapse entry **only when it is not started in the incubator**. This feature allows the user to select another incubator if they made a mistake in choosing the incubator when creating timelapse.

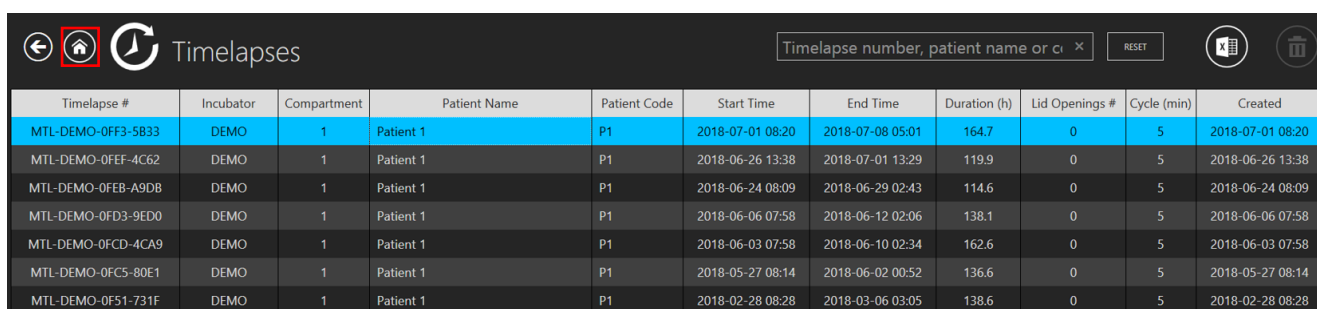


The screenshot shows the 'Timelapses' application interface. At the top, there is a navigation bar with icons for back, home, and a circular arrow. A search bar contains the text 'Timelapse number, patient name or c'. To the right of the search bar is a 'RESET' button and a trash can icon, which is highlighted with a red box. Below the navigation bar is a table with 11 columns: Timelapse #, Incubator, Compartment, Patient Name, Patient Code, Start Time, End Time, Duration (h), Lid Openings #, Cycle (min), and Created. The table contains 8 rows of data, all for 'Patient 1' and 'DEMO' incubator.

Timelapse #	Incubator	Compartment	Patient Name	Patient Code	Start Time	End Time	Duration (h)	Lid Openings #	Cycle (min)	Created
MTL-DEMO-0FF3-5B33	DEMO	1	Patient 1	P1	2018-07-01 08:20	2018-07-08 05:01	164.7	0	5	2018-07-01 08:20
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MTL-DEMO-0FD3-9ED0	DEMO	1	Patient 1	P1	2018-06-06 07:58	2018-06-12 02:06	138.1	0	5	2018-06-06 07:58
MTL-DEMO-0FCD-4CA9	DEMO	1	Patient 1	P1	2018-06-03 07:58	2018-06-10 02:34	162.6	0	5	2018-06-03 07:58
MTL-DEMO-0FC5-80E1	DEMO	1	Patient 1	P1	2018-05-27 08:14	2018-06-02 00:52	136.6	0	5	2018-05-27 08:14
MTL-DEMO-0F51-731F	DEMO	1	Patient 1	P1	2018-02-28 08:28	2018-03-06 03:05	138.6	0	5	2018-02-28 08:28

Figure 7.9 “Delete” button

The “Home” button takes the user to the Main View. This button is available in all menus to ease the navigation and improve user experience.



The screenshot shows the 'Timelapses' application interface. At the top, there is a navigation bar with icons for back, home, and a circular arrow. The home icon is highlighted with a red box. To the right of the search bar is a 'RESET' button and a trash can icon. Below the navigation bar is a table with 11 columns: Timelapse #, Incubator, Compartment, Patient Name, Patient Code, Start Time, End Time, Duration (h), Lid Openings #, Cycle (min), and Created. The table contains 8 rows of data, all for 'Patient 1' and 'DEMO' incubator.

Timelapse #	Incubator	Compartment	Patient Name	Patient Code	Start Time	End Time	Duration (h)	Lid Openings #	Cycle (min)	Created
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MTL-DEMO-0FEF-4C62	DEMO	1	Patient 1	P1	2018-06-26 13:38	2018-07-01 13:29	119.9	0	5	2018-06-26 13:38
MTL-DEMO-0FEB-A9DB	DEMO	1	Patient 1	P1	2018-06-24 08:09	2018-06-29 02:43	114.6	0	5	2018-06-24 08:09
MTL-DEMO-0FD3-9ED0	DEMO	1	Patient 1	P1	2018-06-06 07:58	2018-06-12 02:06	138.1	0	5	2018-06-06 07:58
MTL-DEMO-0FCD-4CA9	DEMO	1	Patient 1	P1	2018-06-03 07:58	2018-06-10 02:34	162.6	0	5	2018-06-03 07:58
MTL-DEMO-0FC5-80E1	DEMO	1	Patient 1	P1	2018-05-27 08:14	2018-06-02 00:52	136.6	0	5	2018-05-27 08:14
MTL-DEMO-0F51-731F	DEMO	1	Patient 1	P1	2018-02-28 08:28	2018-03-06 03:05	138.6	0	5	2018-02-28 08:28

Figure 7.10 “Home” button

The timelapse view shows:

- Timelapse number (unique timelapse identifier).
- Incubator ID (in which MIRI® TL multiroom IVF incubator the specific timelapse was generated).
- Chamber (in which MIRI® TL6 or MIRI® TL12 multiroom IVF incubators chamber the specific timelapse was generated).
- Patient name.
- Patient code.
- Start time (pending if still running).
- End time (pending if still running).
- Duration (h) (pending if still running).
- Lid openings number (counter that counts lid openings in the specific chamber during the timelapse).
- Cycle (min) (the set cycle time between each image stack).
- Created (the date and time when the timelapse file was created).

Timelapse #	Incubator	Compartment	Patient Name	Patient Code	Start Time	End Time	Duration (h)	Lid Openings #	Cycle (min)	Created
MTL-DEMO-0FF3-5B33	DEMO	1	Patient 1	P1	2018-07-01 08:20	2018-07-08 05:01	164.7	0	5	2018-07-01 08:20
MTL-DEMO-0FEF-4C62	DEMO	1	Patient 1	P1	2018-06-26 13:38	2018-07-01 13:29	119.9	0	5	2018-06-26 13:38
MTL-DEMO-0FEB-A9DB	DEMO	1	Patient 1	P1	2018-06-24 08:09	2018-06-29 02:43	114.6	0	5	2018-06-24 08:09

Figure 7.11 Timelapse menu

The timelapse film can be entered here by double-clicking on the specific timelapse that the user wants to open.

7.3.2 Timelapse view

A timelapse data file is opened either from the main timelapse list view (by double clicking the desired timelapse), the specific patient view or the specific patient treatment view.

When opened, a revolver view with the movie files will be presented.

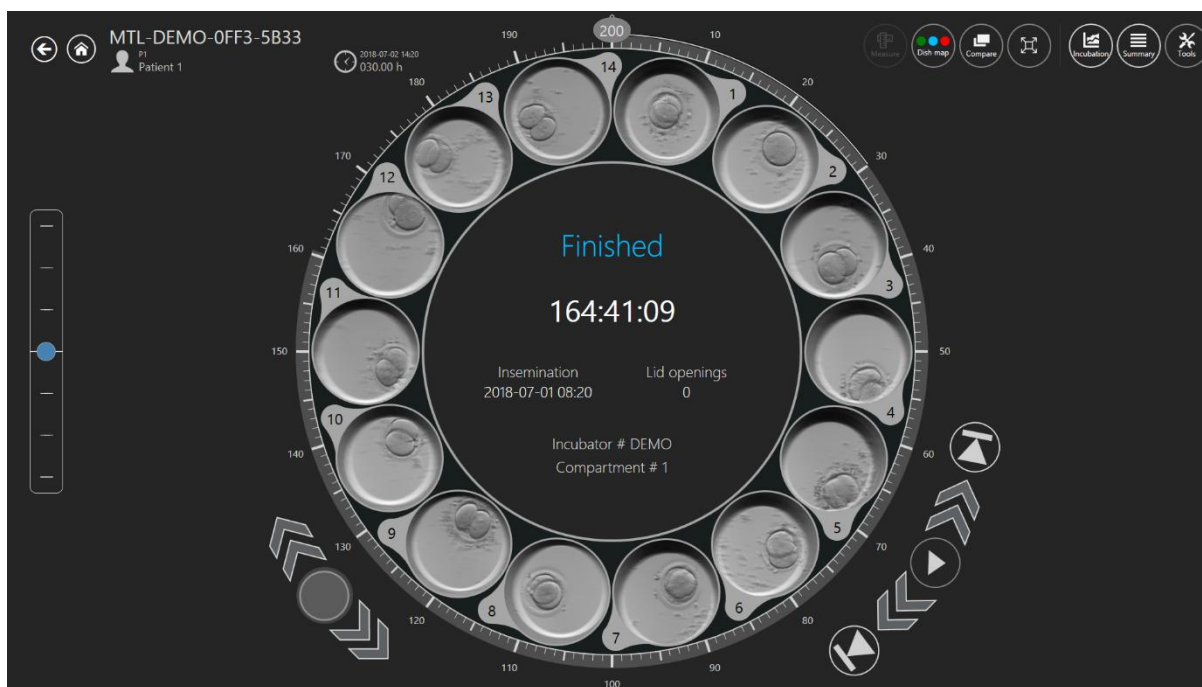


Figure 7.12 The timelapse view of a specific patient

The view contains the 14 wells of one single CultureCoin® dish. Sometimes the well can be displayed as inactive (see Figure 7.13), and the user will not be able to select it. In order to activate or inactivate a specific well, please refer to the “User Manual of MIRI TL family’s multiroom IVF incubators”.



Figure 7.13 Inactive well designation

When the well is active, the user can select it, and it will be displayed in the middle of the revolver view. Clicking on the active well allows for annotation, measurement, comparison, and more while also enlarging the well view.

In the middle of the view, there is an area where some necessary information is provided, such as:

- Incubator number.
- Chamber number.
- Insemination time.
- Lid openings during the timelapse.
- The timelapse status: “Pending” or “Finished”.

In the upper left corner of the Timelapse view, the timelapse ID number and patient information are provided.

To the left of the revolver view, the focal plane shifter is located.

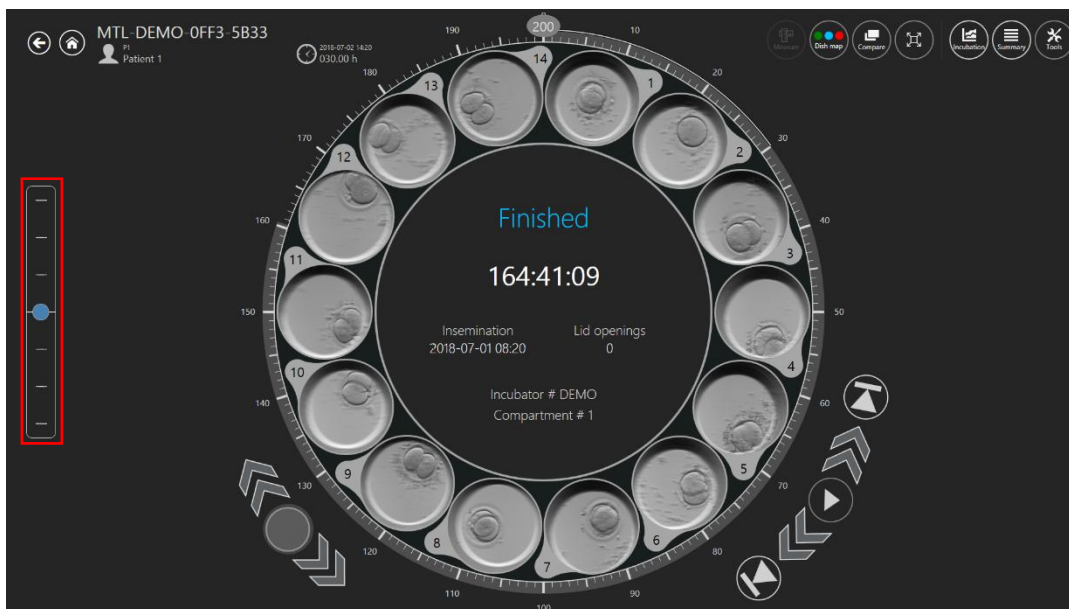


Figure 7.14 Focal plane shifter

It has the number of steps the timelapse movie was generated in (i.e., 3, 5 or 7). Using the finger or the mouse, the user can move the blue marker up and down to shift all movies simultaneously through all possible focal planes. Focal planes cannot be shown separately for different wells. All 14 wells will be on the same focal plane at all times.

Five video player controls are located at the bottom right, near the main revolver view. They enable the user to move through the film, pause it, hit play or jump to the start or the end of it.

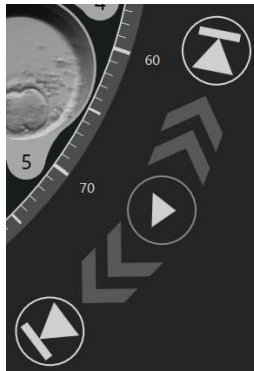


Figure 7.15 Video player controls

The circular time indication around the revolver view can also be used to select the desired time quickly. The selected time is displayed to the top left of the revolver view, near the 13th well.

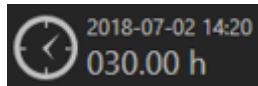


Figure 7.16 Selected time

Well navigation controls are located at the bottom left of the revolver view. There, a number of the currently selected well are displayed, as well as arrows that allow the user to navigate to the next/previous well of the CultureCoin®.



Figure 7.17 Well navigation controls

👉 It is also possible to use a two-key combination on the keyboard (left Alt + left/right arrow buttons) to jump to the next well.

When the specific well in the active timelapse is stopped at a particular time in the MIRI® TL family's multiroom IVF incubator LiveView mode, the Viewer software will indicate it in the timelapse view. The software will show the square symbol and the specific time when the timelapse was stopped.

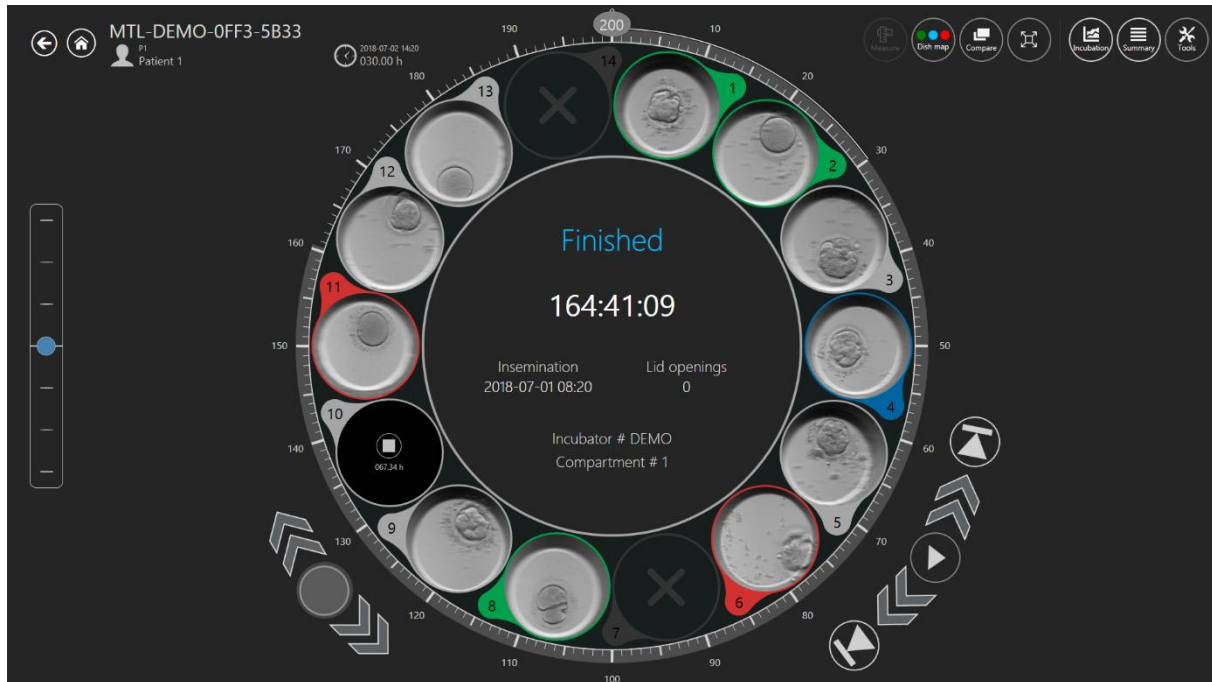


Figure 7.18 The timelapse view of a specific patient with 1 stopped timelapse

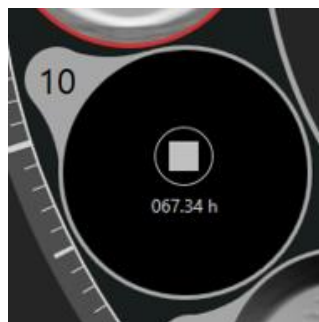


Figure 7.19 The view of the timelapse, which was stopped at 67.34h

7.3.2.1 Annotations

The user can left-click on any well with an embryo in it to enlarge the well to the middle of the revolver (move it to the “active area”). This action alters the view of the menu a bit where the user can start using the integrated annotation system. It is structured around “Events” located in the menu to the left of the revolver wheel.

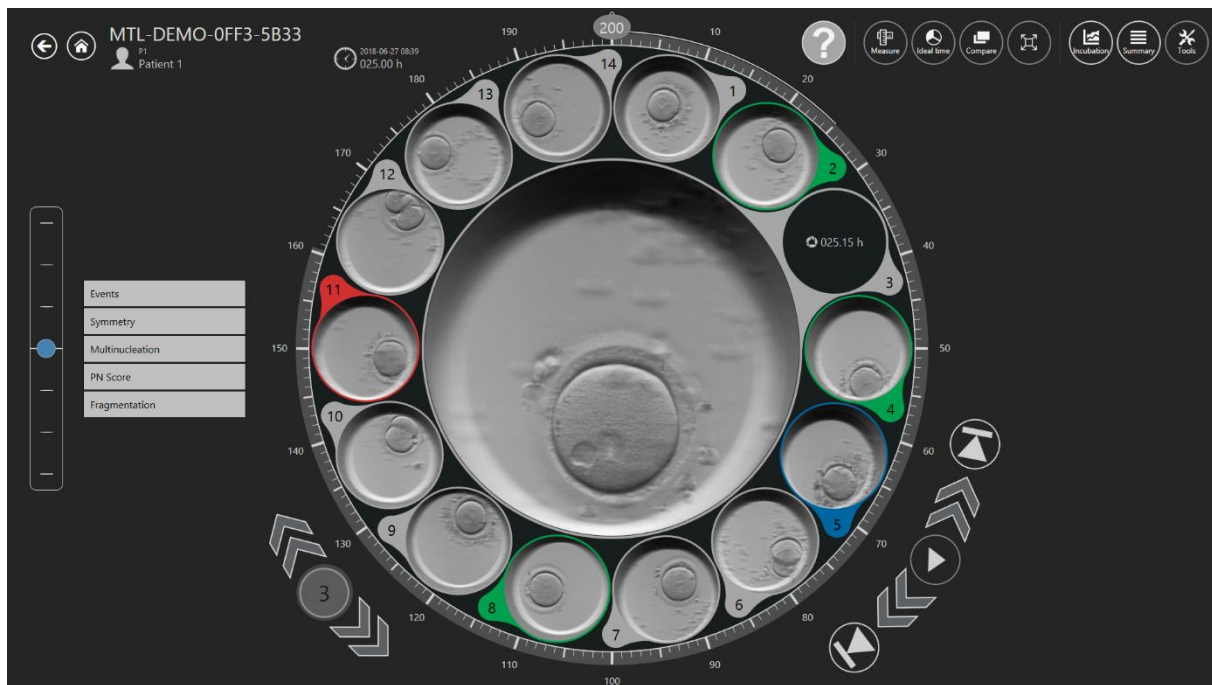


Figure 7.20 Timelapse annotation's view

 A well number of the currently selected CultureCoin® well becomes visible inside the well navigation controls.

When the user observes an event taking place in the film, for instance, sees the division to a 2-cell embryo – then the user will double-click the “t2” under the event list.

 It is possible to use a two-key combination on the keyboard (left Control + left/right arrow buttons) to jump to the next annotation.

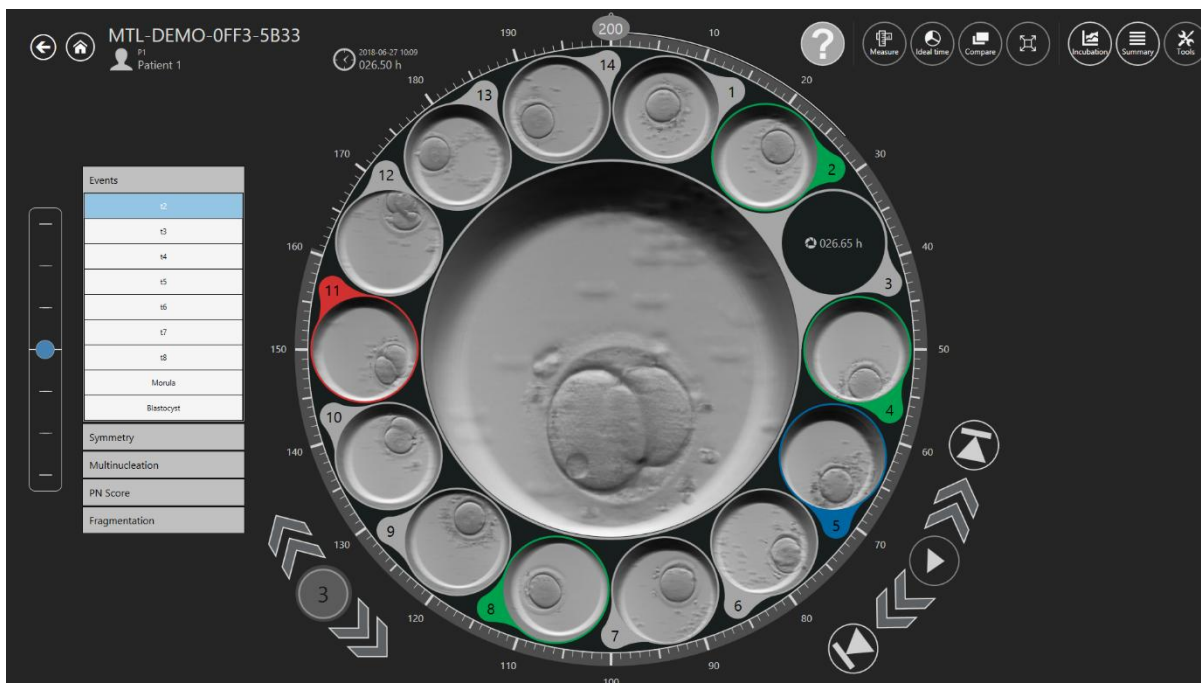


Figure 7.21 The view before adding the new event

Now the t2 will move to the Timelapse view's right side, and the timeline until the event will be colored with appropriate annotation color.

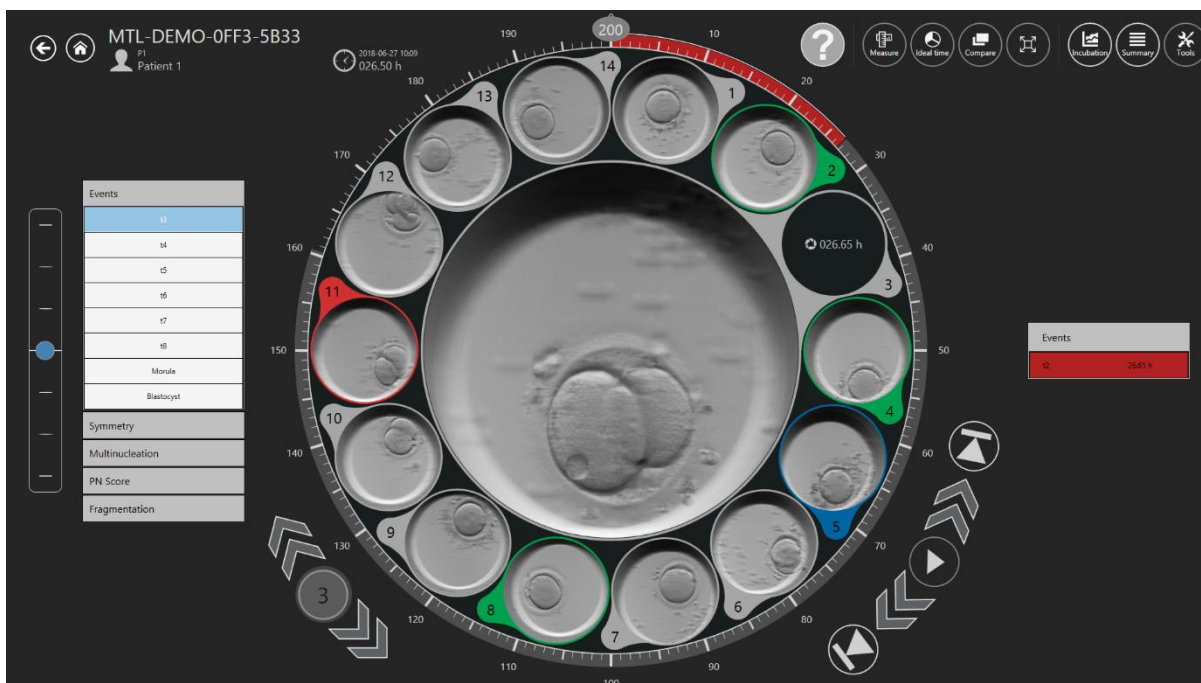


Figure 7.22 The view after adding the new event

When all events have been assigned a time, the embryo has been annotated. How many events (level of annotation) the user wants to use is entirely at their discretion and dependent on the selection criteria that the clinic uses. Any incorrect annotation can quickly be moved back (deleted) by double-clicking on it on the result side.

Annotations are stored in the database.

Annotations can be user customized (please refer to the “7.6.1 Annotation modification/creation” section of the User Manual for more details).

In the default form the annotation menu contains (see Figure 7.23):

- Events (t2 – t8, Morula, Blastocyst)
- Symmetry (Even or Uneven)
- Multinucleation (MN 1c, MN 2c)
- PN score (1PB, 2PB, 2PN, Syngamy, PN Fading, 1PN, Z1, Z2, Z3, Z4, Central, Central Side, Side)
- Fragmentation (5%, 10%, 15%, 20% or Reversal)

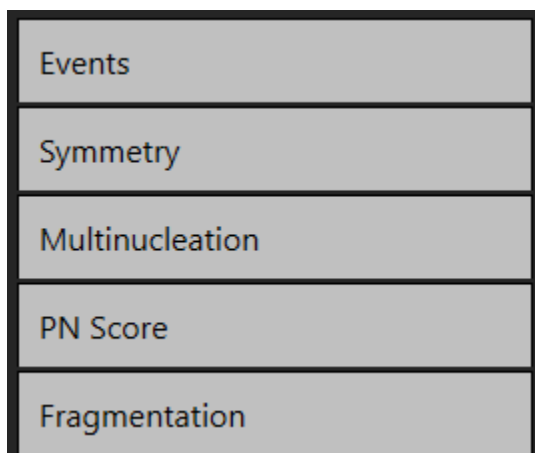


Figure 7.23 The annotation menu

Events’ results will be automatically calculated and will appear in the “Summary view” result list and “Report” annotation group table once the events have been assigned a time. For instance, “Report” annotation group table can show cell cycle’s time difference between certain cell divisions, i.e., $cc2 = t3 - t2$; $cc3 = t5 - t3$.

<div>5</div> <div>Events</div> <div>two cells 7.88 h</div> <div>t3 33.21 h</div> <div>t4 33.46 h</div> <div>t5 50.21 h</div> <div>t6 52.88 h</div> <div>t7 54.63 h</div> <div>t8 60.46 h</div> <div>Measurement</div> <div>Measurement 0.15 h</div> <div>Calculations</div> <div>cc2 25.33 h</div> <div>s2 0.25 h</div> <div>cc3 17.00 h</div> <div>s3 10.25 h</div>	ANNOTATION GROUP	NAME	TIME
	Events	two cells	7.88h
		t3	33.21h
		t4	33.46h
		t5	50.21h
		t6	52.88h
		t7	54.63h
		t8	60.46h
	ANNOTATION GROUP	NAME	TIME
	Measurement	Measurement	0.15h
	Calculations	cc2	25.33h
		s2	0.25h
		cc3	17h
		s3	10.25h

Figure 7.24 Cell division time calculations in the Summary view and Report

In the picture below, the embryo is in the active area. The event list is open and t2 has been assigned a time, therefore it was moved to the result (i.e has been annotated).

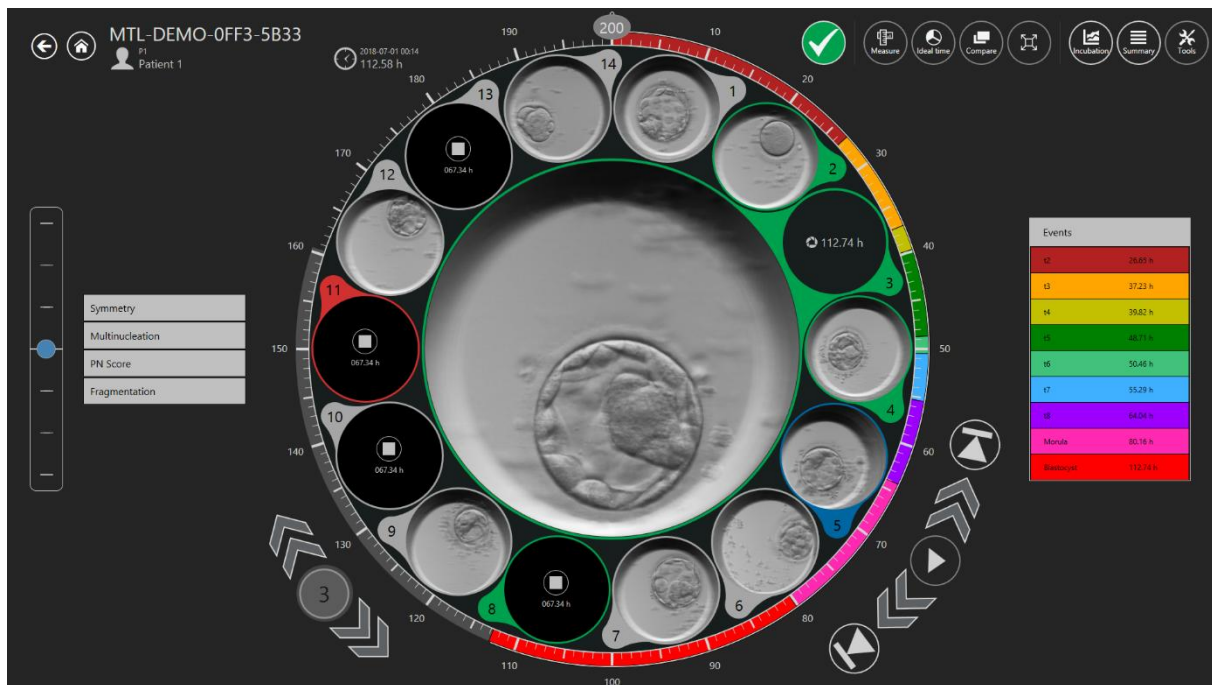


Figure 7.25 Selected “two cells” event annotation

Once the selection process has been completed (or the process results are exact at an early stage), the embryos can be assigned with colors that indicate the decision.

No color means no decision, green means transfer, red means discard, blue means freeze. The “A” embryo state is inactive and displayed in a darker font; all other embryo states are active and are shown normally in the picture below.

The assignment is done on the icon at the top right (see Figure 7.26).

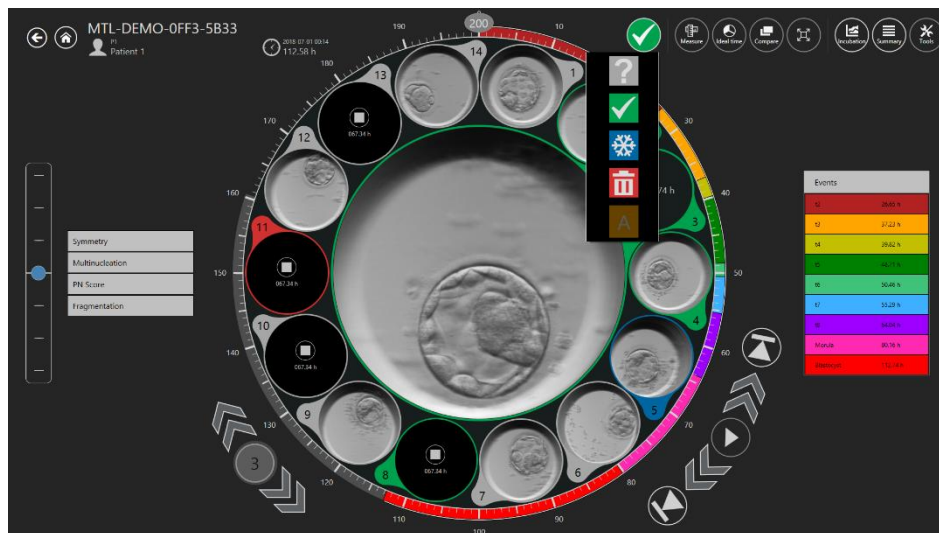


Figure 7.26 The embryo status selection

Clicking on it makes a drop-down list where the desired status can be chosen. A colored ring will appear around the embryo well and the color of the position on the dish map will also change.

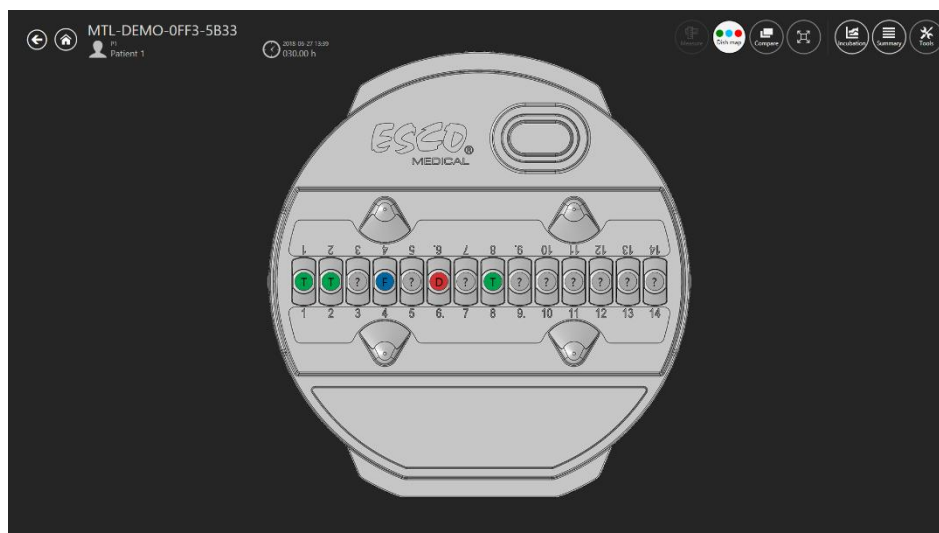


Figure 7.27 The dish map

7.3.2.2 Embryo measurement

There is a “Measure” button in the upper right corner of the main timelapse view. Only when the desired well is in the “Active area” of the revolver, the “Measure” button will be activated. Otherwise, the button will be inactive. Also, the “Dish map” button will change to the “Ideal time” button.

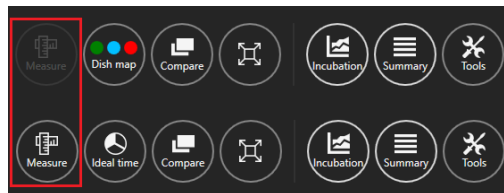


Figure 7.28 Active and inactive “Measure” button on the MIRI® TL Viewer

After pressing on the “Measure” button, three new measurement options will appear.



Figure 7.29 Three measurement options

There is a possibility to choose from 2 types of line and 1 circle measurement. It is also possible to select the color for the desired embryo measurement for easier designation.

 When the 3 measurement options appear, the user can not make annotations and the previous functions will be unavailable.

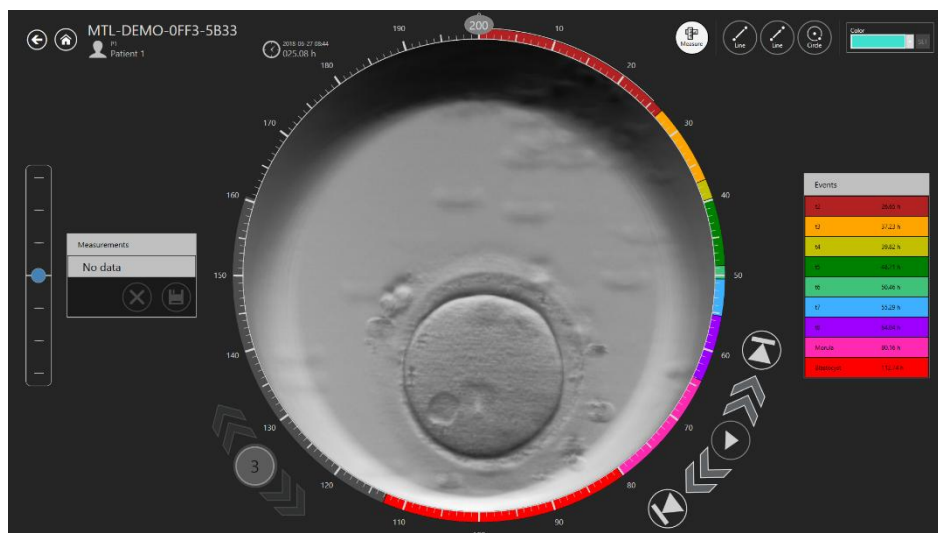


Figure 7.30 Full measurement view

In the picture below, 3 added measurements can be seen on the timelapse image.

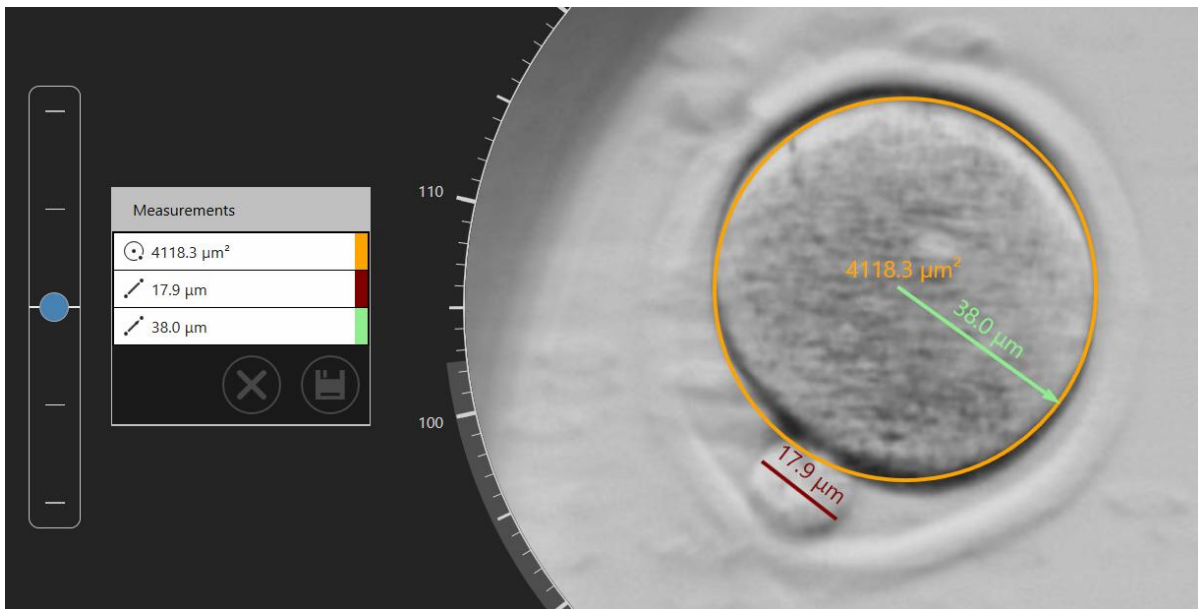


Figure 7.31 Added measurements on the timelapse image

Double-clicking an unwanted measurement can be used to delete it. Pressing the “x” button will delete **all the measurements**.

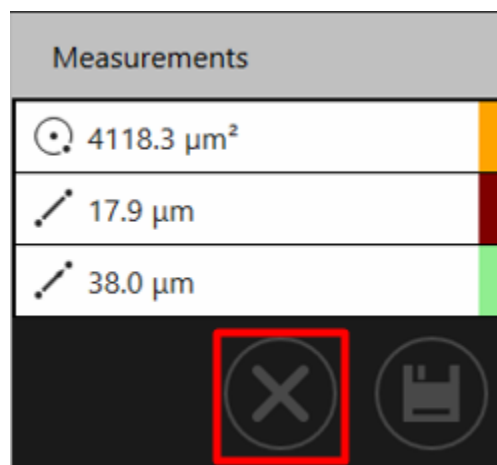
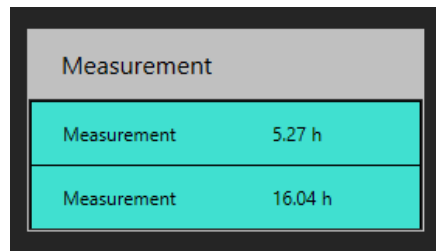


Figure 7.32 The “x” button

When the measurements are saved, “Measurements” will appear on the right side of the main timelapse view.

👉 When a measurement is created, or an existing one is adjusted, the user cannot change the current displayed time (i.e., the time slider is inactive) until the measurement changes are saved or cancelled.



Measurement	
Measurement	5.27 h
Measurement	16.04 h

Figure 7.33 Example of measurements done at a specific time

7.3.2.3 Dish map

The “Dish map” button opens a view that shows the embryos' location in the CultureCoin® dish and the selected embryo state. The dish map can be printed or used during the transfer or handling of the embryos.

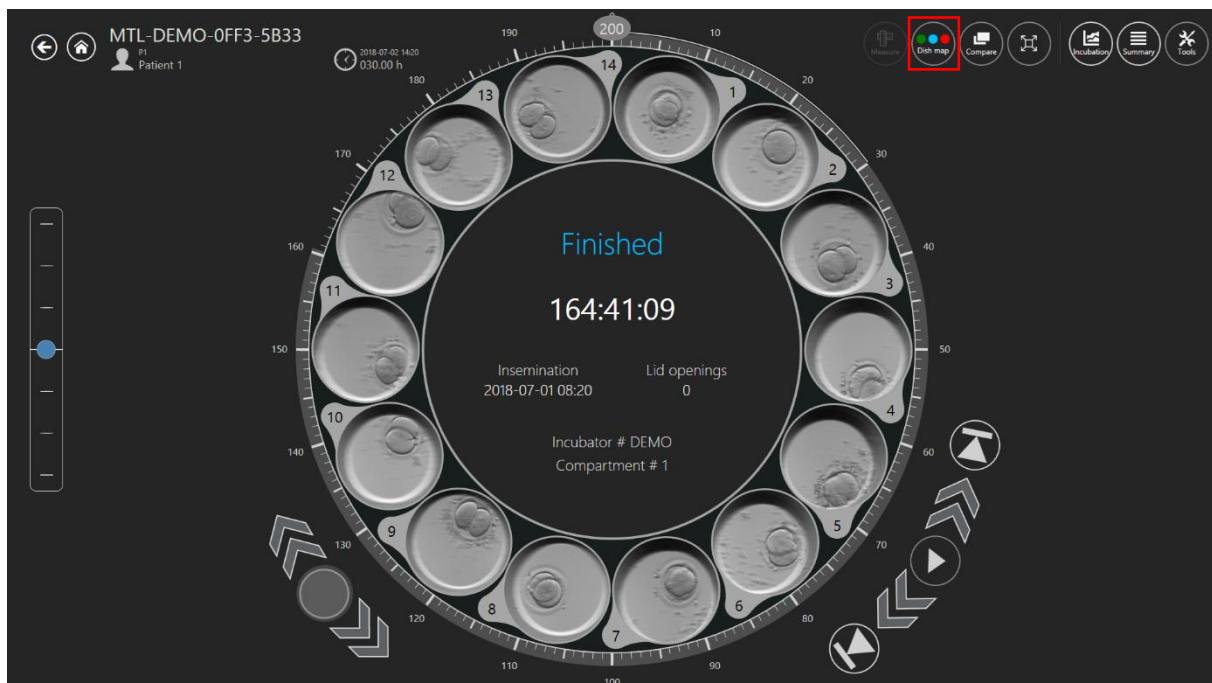


Figure 7.34 “Dish map” button

👉 Make sure to deselect any well from the “Active area” to see the “Dish map” button.

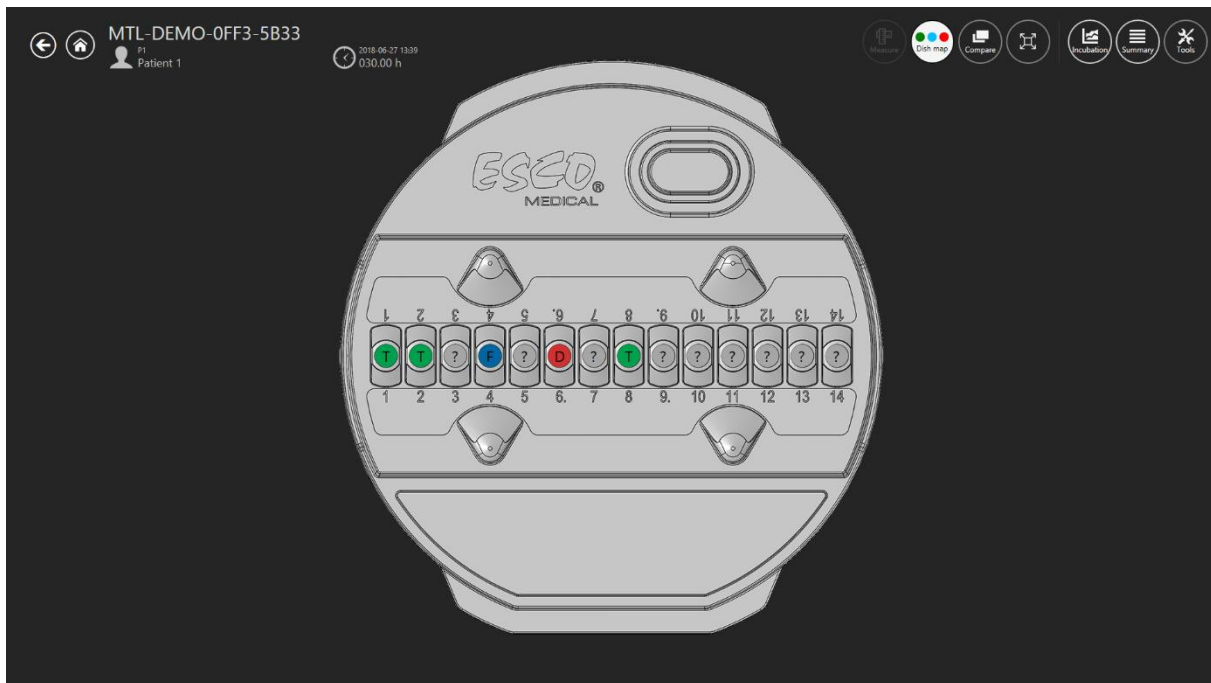


Figure 7.35 The dish map

Green color (T) means that the embryo is suitable for transfer, red (D) - for discarding, blue (F) for freezing and the “?” mark means that the user did not choose the embryo state.

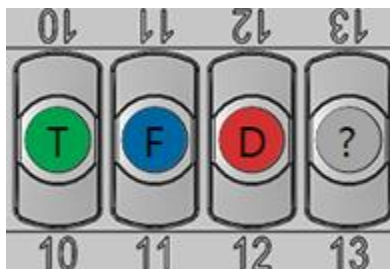


Figure 7.36 Dish map annotation options

7.3.2.4 Ideal time

The ideal time button turns a ring around the revolver wheel “ON/OFF”. It colors the “Ideal” time length of a specific event (shown in Figure 7.37 below).

For instance, if the ideal time for the t2 stage should be 28 hours, the colored line will stop at the time mark for 28. A quick visual comparison is now possible between the ideal and the annotated parameter. The closer the parameters match, the more ideal the embryo is.

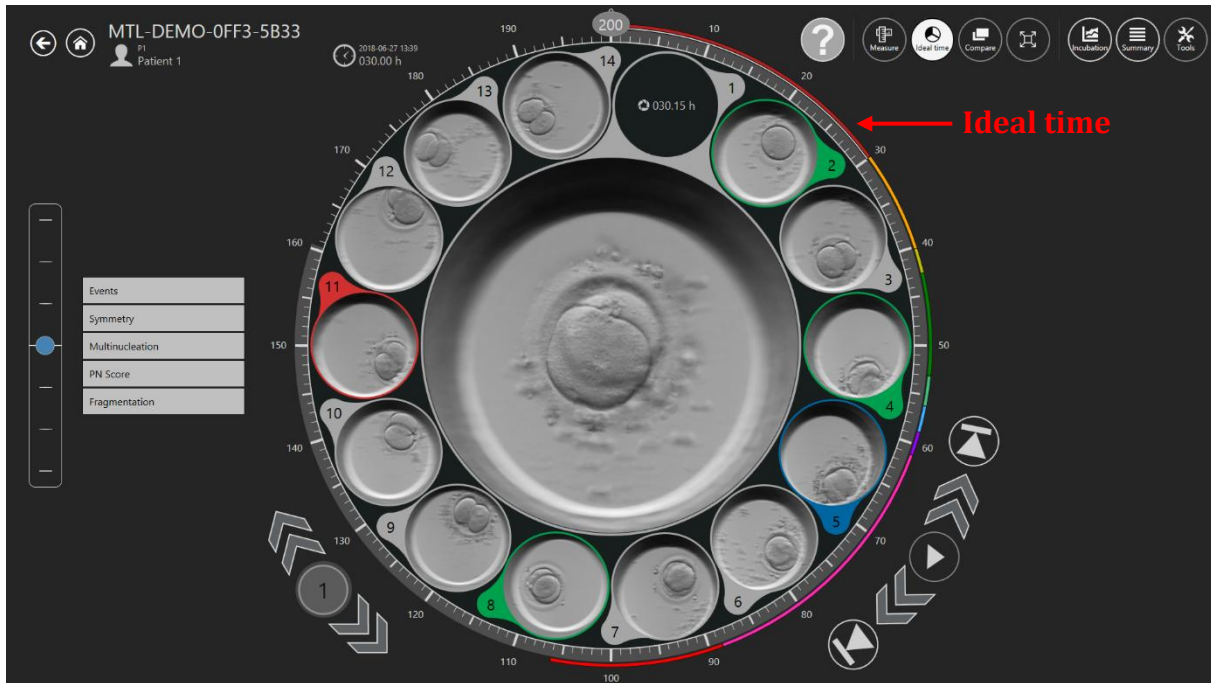


Figure 7.37 The ideal times shown around the revolver

The user can set up the ideal times himself as the parameters may differ for different clinics due to different methodologies.

Please refer to the “7.6.1 Annotation modification/creation” section of the User Manual for more guidance on how to change a specific event's ideal times.

7.3.2.5 Embryo comparison

The “Compare” button makes it possible to maximize up to six embryos side by side for a more detailed comparison if it is difficult to make a selection.

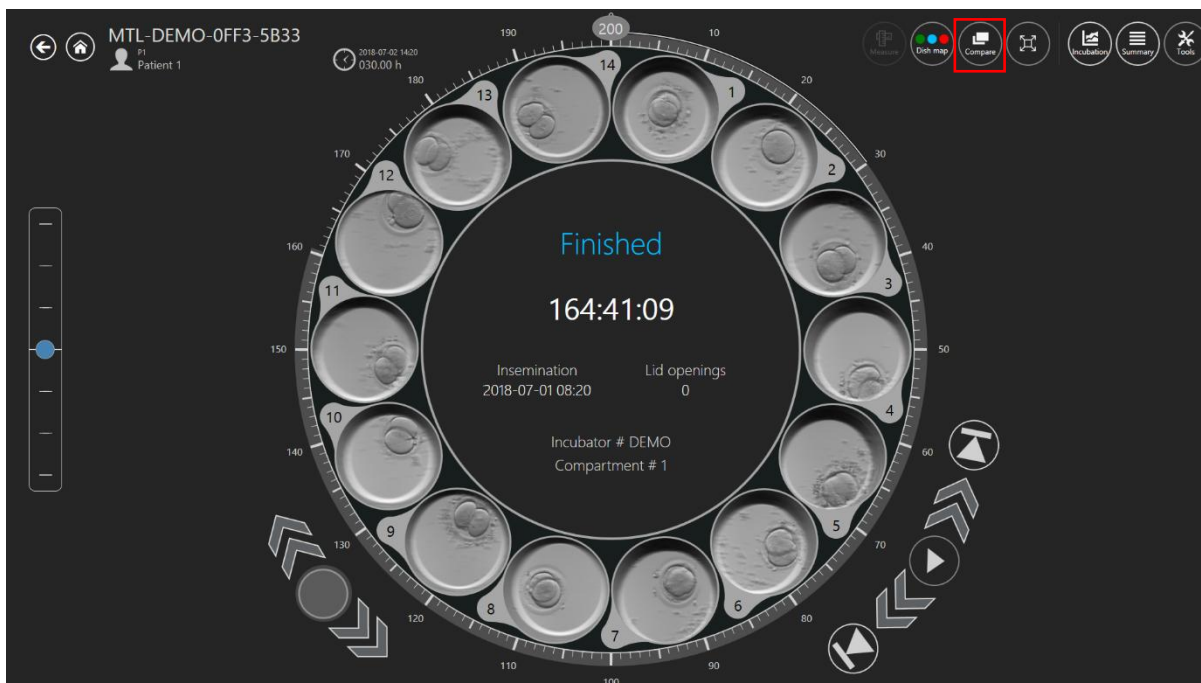


Figure 7.38 “Compare” button

Click the “Compare” button, then select one well (if the well hasn’t already been selected). It will be displayed in the center. Then choose another well you are interested in from the rest. Selecting the second well will change the display to the Compare view.

While in the Compare view, it is possible to select additional wells (up to 6 overall) to compare at the same time.

 **When selecting more than 2 wells, the overall size of the well is reduced.**



Figure 7.39 Compare view of two embryos



Figure 7.40 Compare view of multiple embryos

The video players can be played independently or linked by pressing the “Link” button at the top right of the screen. After linking the videos, video controls become available only near the 1st well.



Figure 7.41 The linked “Compare” view

7.3.2.6 Image maximization

The “Maximize” button will place the selected well in the center of the revolver for a clearer visualization of a particular well. To the bottom left, well navigation controls are located. There, a number of the currently selected well is displayed, as well as arrows that allows the user to navigate to the next/previous well of the CultureCoin®.

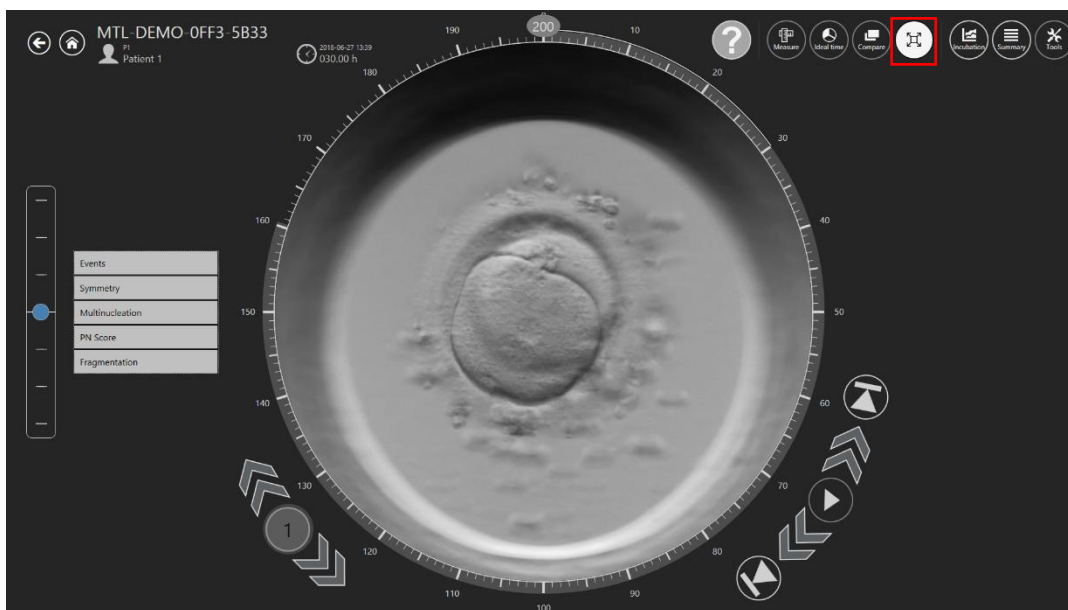


Figure 7.42 The “Maximize” button and the subsequent view

7.3.2.7 Incubation data logging

The “Incubation” button shows the incubation data for the MIRI® TL family’s multiroom IVF incubator where the CultureCoin® was or is.

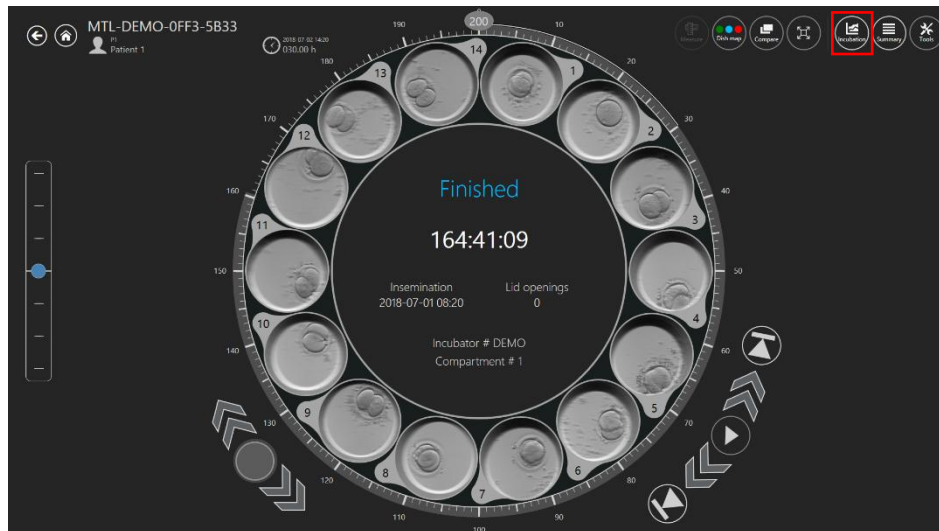


Figure 7.43 “Incubation” button

Incubation data is displayed here from when the timelapse was performed.

The user can select between temperature, CO₂, O₂ and alarms incubation data log in the top left corner.

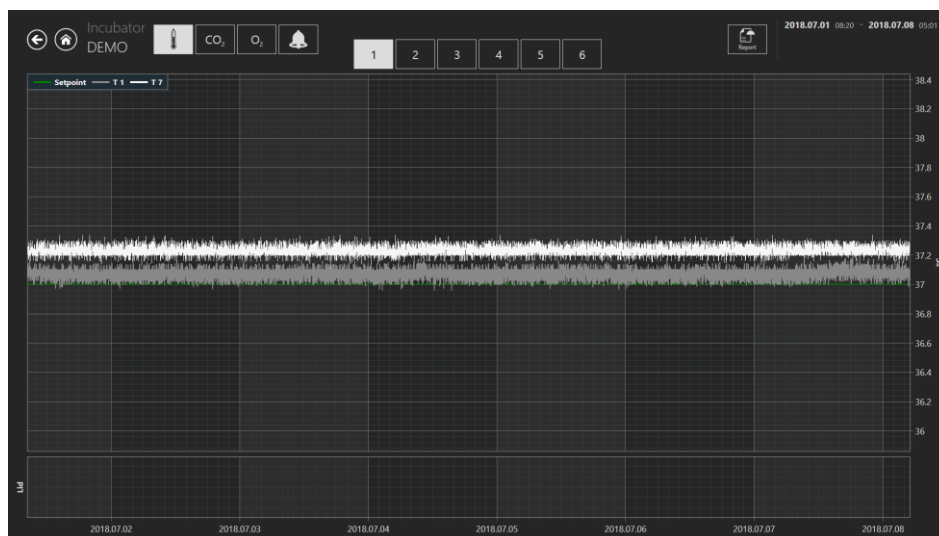


Figure 7.44 Temperature incubation view

There are buttons from 1 to 6 at the top, where the user can choose the desired chamber. In this case, chamber number 1 is selected. It will show the setpoint in addition to the T1 and T7 zones temperature values.

A zoom function is available by touching the screen and swiping the finger (or with a computer mouse) left over the area that should be zoomed. Pressing the zoom-out button (marked with a red rectangle) the view will jump back to full.

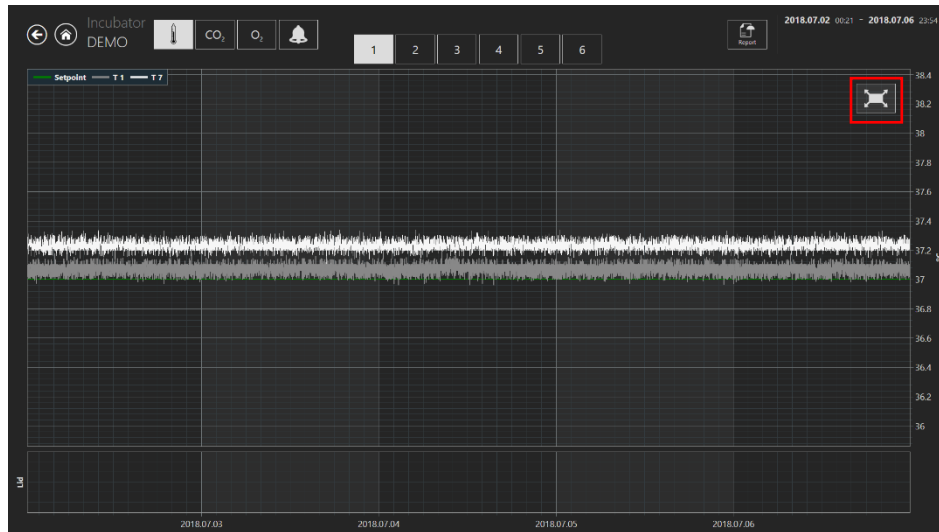


Figure 7.45 “Reset” button

Pressing the CO₂ button will shift from the temperature data view to the CO₂ gas data view.

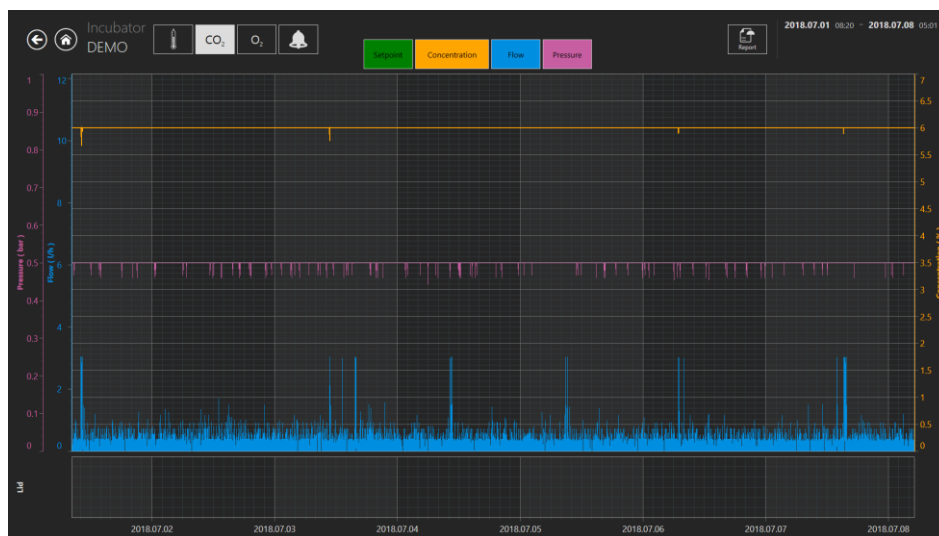


Figure 7.46 The CO₂ data view

The user can see the historical data of CO₂ gas concentration setpoint, concentration, flow and pressure.

Pressing the O₂ button will shift from the CO₂ gas data view to the O₂ gas data view.

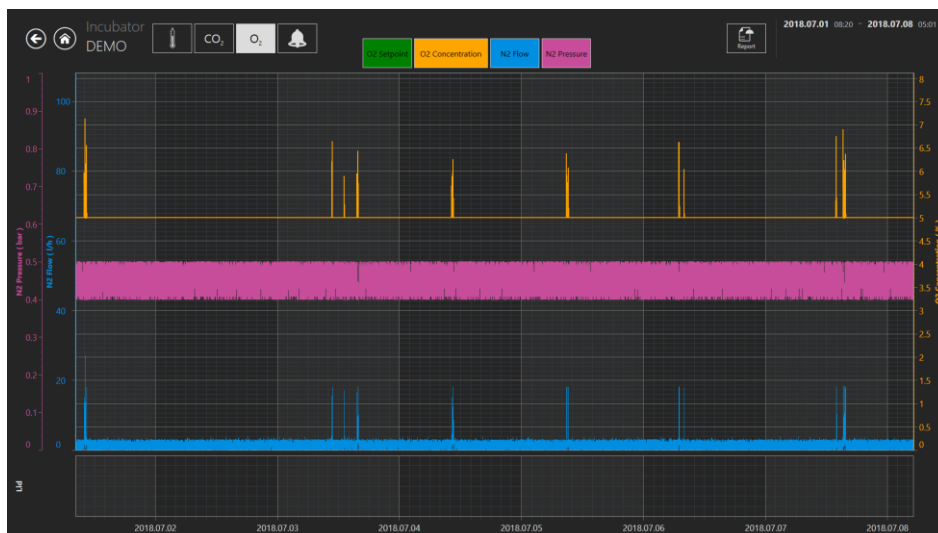


Figure 7.47 The O₂ data view

The user can see historical data of O₂ gas concentration setpoint, concentration, N₂ gas flow and pressure.

The “Alarm” button will bring up the graphical alarm view.



Figure 7.48 The graphical “alarm” view

The “Report” button will bring up the report mode. All running parameters can easily be documented and printed as a report or exported to PDF, Excel or Word for convenient ISO quality

management compliance. (for more information, please refer to the “7.3.2.9 Export function” section of the User Manual).

7.3.2.8 Summary view

The summary view consists of two different graphical representations that show the user's annotations in direct comparison.

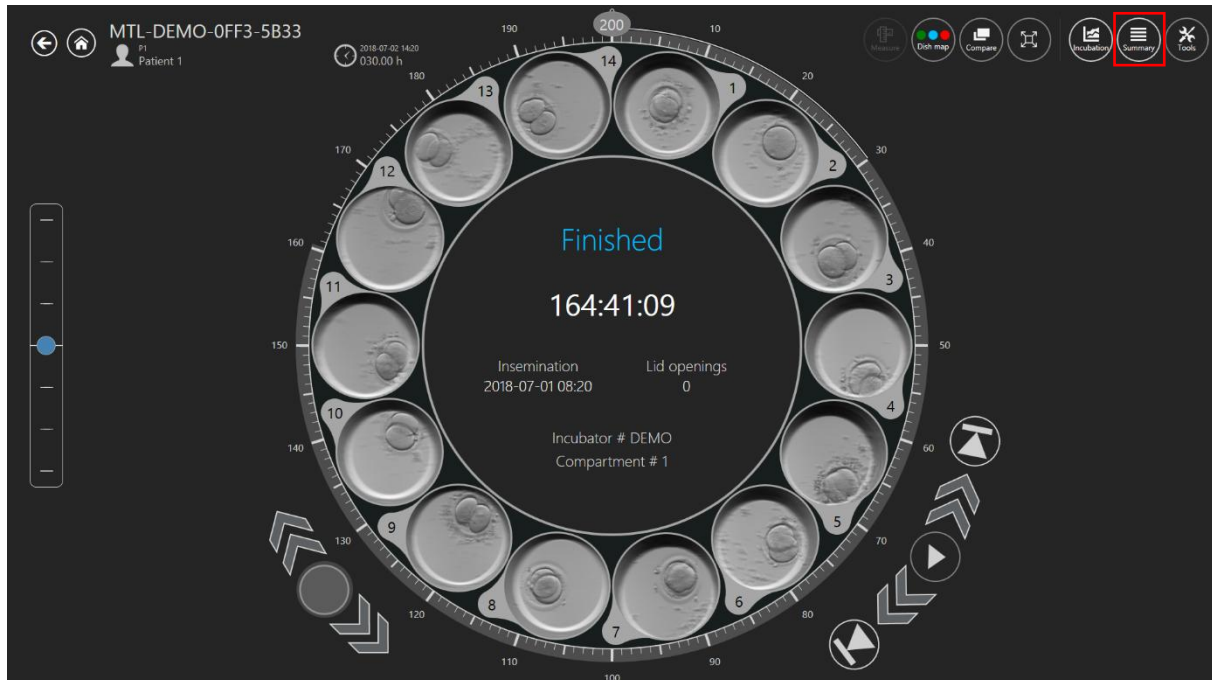


Figure 7.49 “Summary” button

In the first view that opens up, all active wells are shown as different lines aligned from the top to the bottom in the ascending order with their numbers at the left. In an example (see Figure 7.50), well number 1 is first. Annotations made for well number 1 are portrayed horizontally and discerned by different colors. After well number 1 (going down) is well number 2 and the annotations for that well are portrayed in a similar fashion. The principle is applicable to other wells as well.

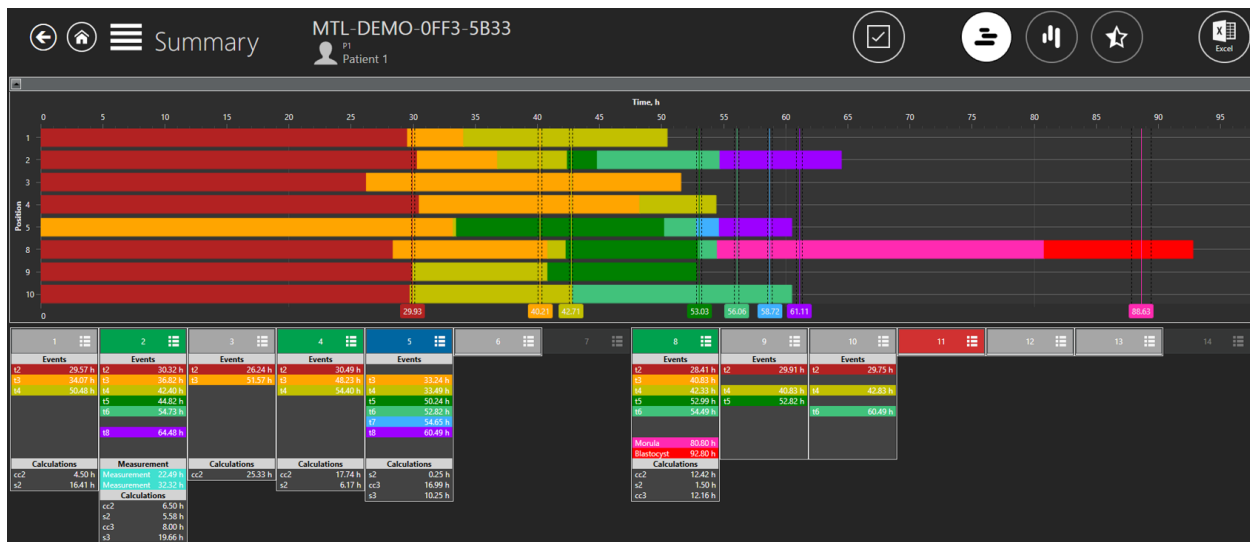


Figure 7.50 All selected dish positions in a summary view

The ideal times are shown as vertical lines with a tag on and a color representing them.

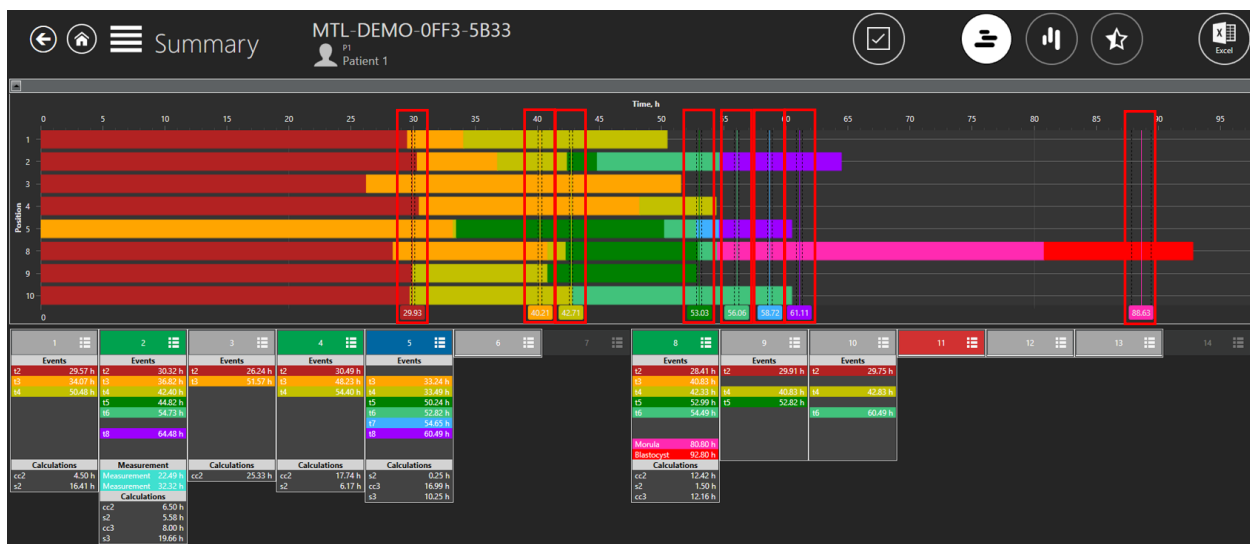


Figure 7.51 Ideal times

The wells numbers are listed under the graphical lines at the top of the different boxes where the annotated events are shown in text and in different colors stacked vertically.

There is a possibility to select/deselect all dishes by clicking on a checkmark in the summary view.

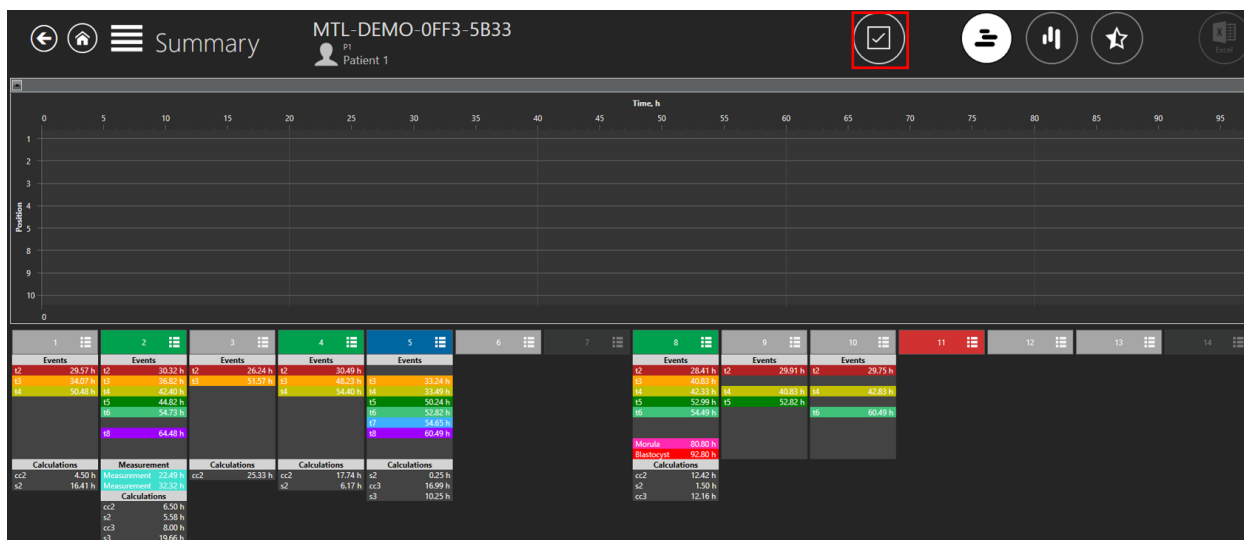


Figure 7.52 All deselected dish positions in a summary view

Well's portrayal on the graphical line can be toggled "ON/OFF" by pressing anywhere on the listed annotation information of the desired well. When selected, the dish box will have a white outline. Information in boxes that do not have a white outline, will not be displayed in the horizontal view.

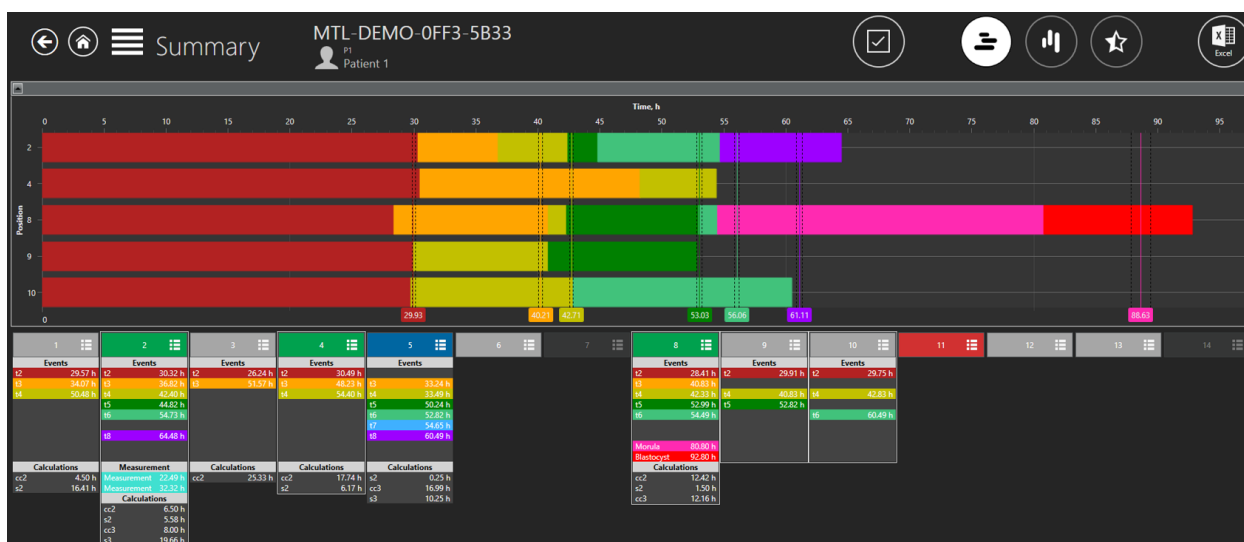


Figure 7.53 2, 4, 8, 9, 10 wells selected in the summary view

Events' annotations are aligned for easier comparison, but different measurements and calculations derived from annotations are listed normally (i.e. not aligned).

1	2	3	4	5
Events	Events	Events	Events	Events
t2 29.57 h	t2 30.32 h	t2 26.24 h	t2 30.49 h	
t3 34.07 h	t3 36.82 h	t3 51.57 h	t3 48.23 h	t3 33.24 h
t4 50.48 h	t4 42.40 h		t4 54.40 h	t4 33.49 h
	t5 44.82 h			t5 50.24 h
	t6 54.73 h			t6 52.82 h
	t8 64.48 h			t7 54.65 h
				t8 60.49 h
Calculations	Measurement	Calculations	Calculations	Calculations
cc2 4.50 h	Measurement 22.49 h	cc2 25.33 h	cc2 17.74 h	s2 0.25 h
s2 16.41 h	Measurement 32.32 h		s2 6.17 h	cc3 16.99 h
	Calculations			s3 10.25 h
	cc2 6.50 h			
	s2 5.58 h			
	cc3 8.00 h			
	s3 19.66 h			

Figure 7.54 Event annotation are in alignment

It is possible to work with the status selection in this view. When clicking on the well number 1, the user can set the selection status for the well in a list that will open (the click must be on the field with a well number in it, not below where the listed annotation information can be found).

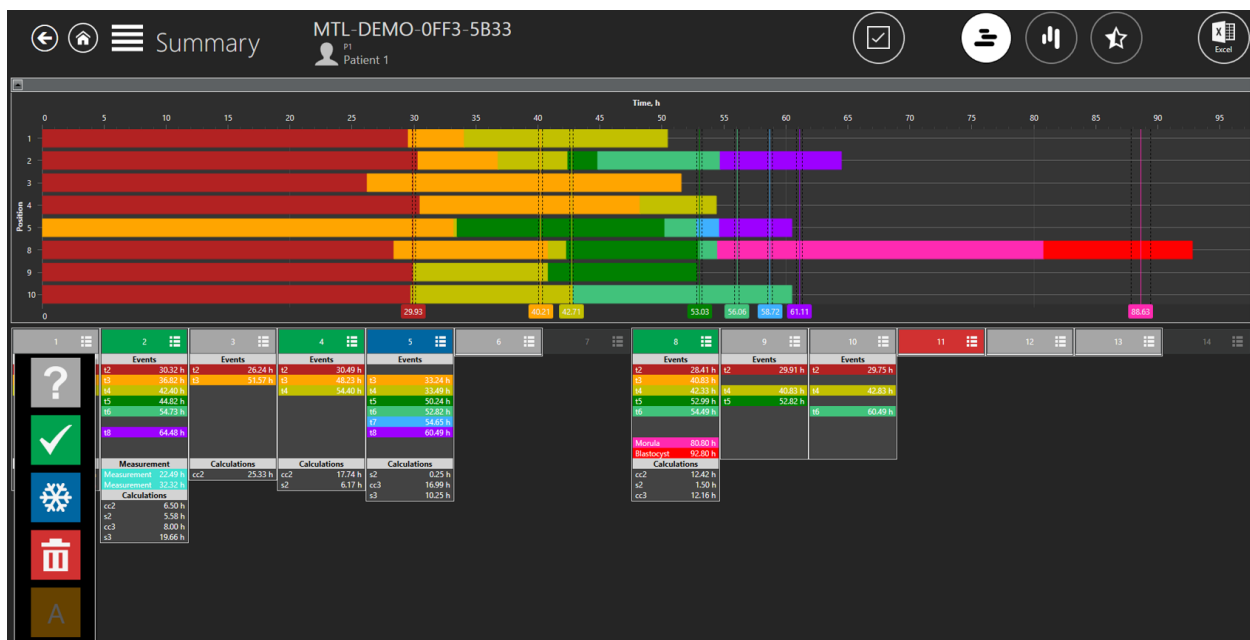


Figure 7.55 Dish status selection option in a vertical summary view

Here, the status of the list can be set. It will change the color in the annotation view and the dish map. The "A" status, is inactivated in the settings, so the image is in a darker font. The user cannot select it.

The second summary view lists the events vertically in the top section. Under each event, the deviation from the ideal time is shown for each of the 14 wells. If the deviation is > 100%, the line will turn red.

👉 At the moment, it is not possible to easily distinguish which deviations belong to which wells. Generally, deviations are arranged from left to right for each of the 14 wells.

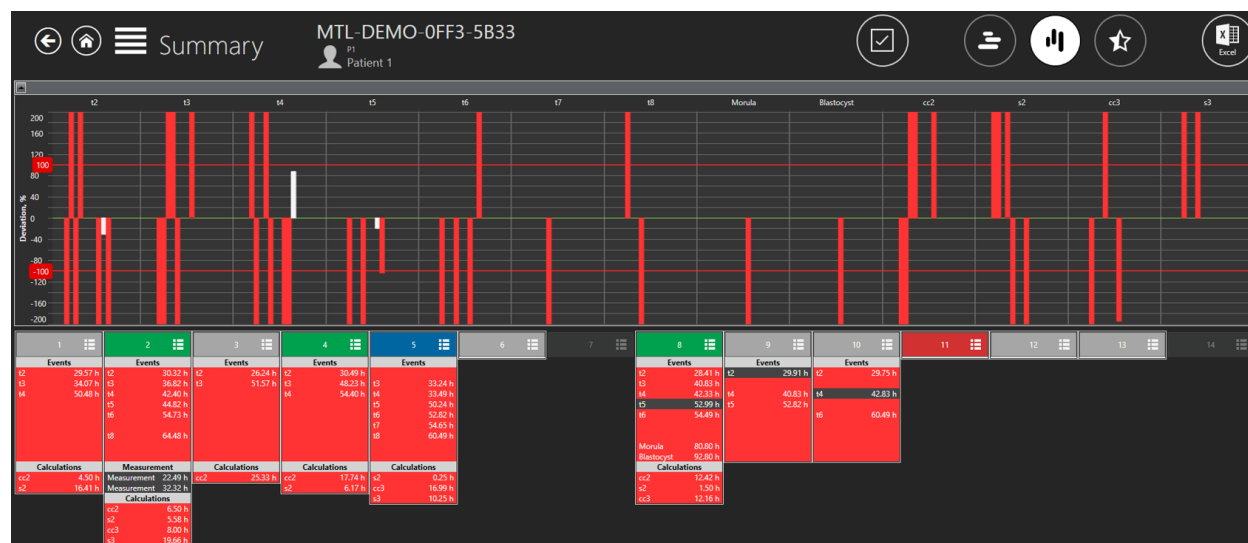


Figure 7.56 Vertical summary view

Again, well's graphical representation can be toggled "ON/OFF" by pressing anywhere on the listed annotation information.

In this instance, there are many cases where the deviation reaches 200%, therefore the difference between the annotated and the ideal time is 200%.

It is possible to work with the status selection in this view. When clicking on the well number 1, the user can set the selection status for the well in a list that will open (the click must be on the field with a well number in it, not below where the listed annotation information can be found).

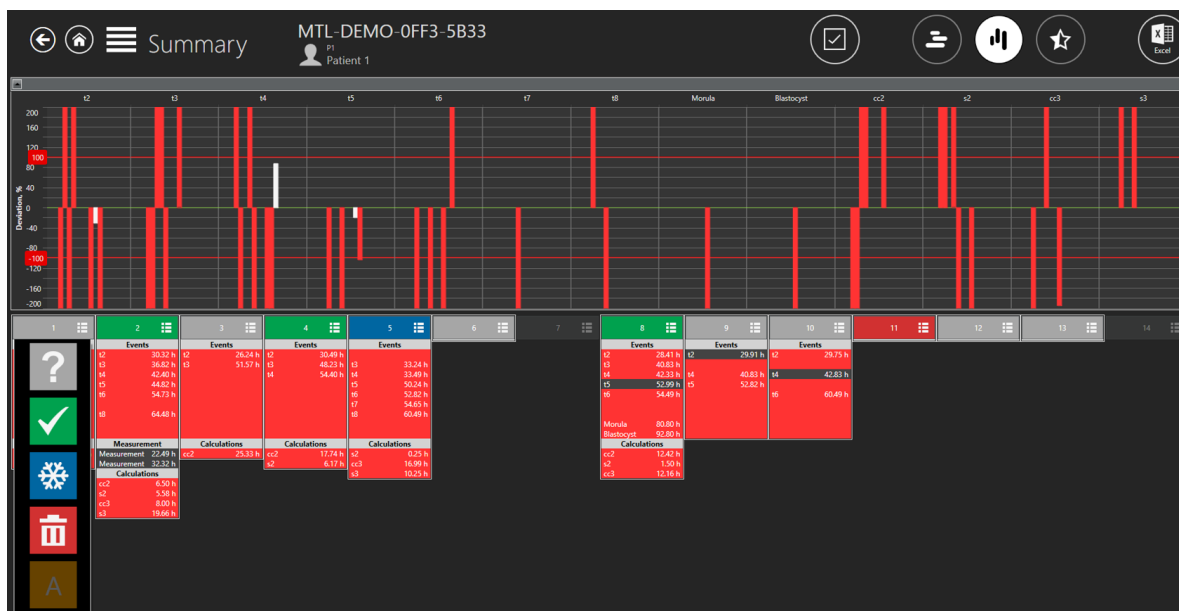


Figure 7.57 Dish status selection option in a horizontal summary view

Here the status can be set. It will change the color in the annotation view and the dish map. The “A” status, in settings, is chosen to be inactive, so the image is in a darker font. The user cannot select it.

7.3.2.8.1 Embryo score model summary view

The user can access the embryo score model summary view by pressing a “Star” button at the top of the summary view.

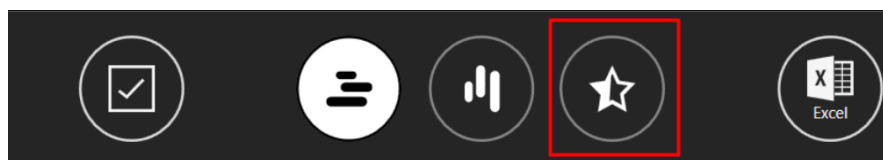


Figure 7.58 “Star” button in a summary view

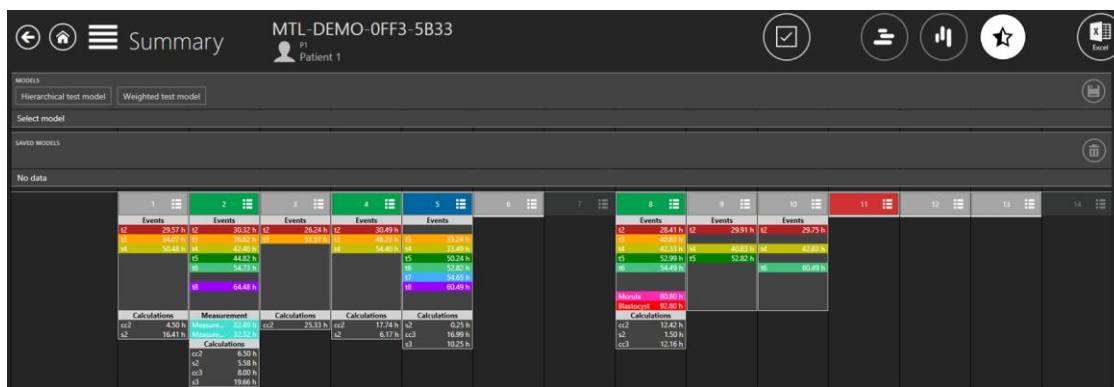


Figure 7.59 Embryo score model summary view

Linking score model to a timelapse

At the top of the screen, the user can see all active embryo score models that were created in the “Settings” menu.

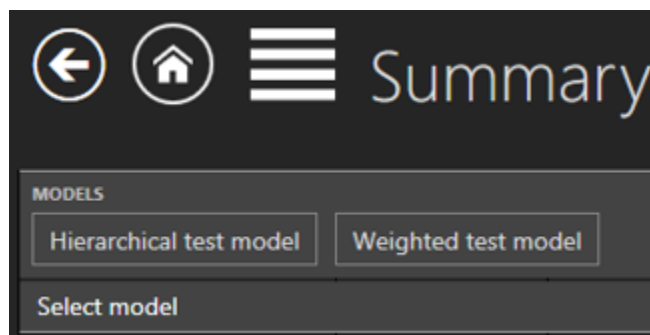


Figure 7.60 List of all created embryo score models

The selected embryo score model will turn white when it is selected.

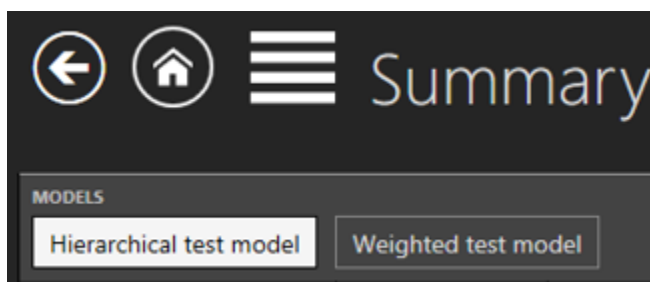


Figure 7.61 Selected “Hierarchical test model”

When the desired embryo score model is selected, the embryo model evaluation will be displayed and the “Save” button will become active.

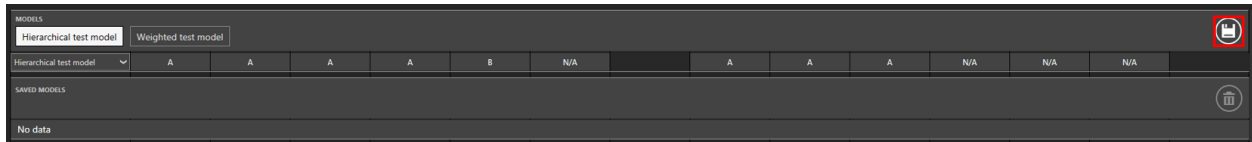


Figure 7.62 “Save” button

When pressed, the embryo score model is linked to a timelapse and will be placed below the list of models.

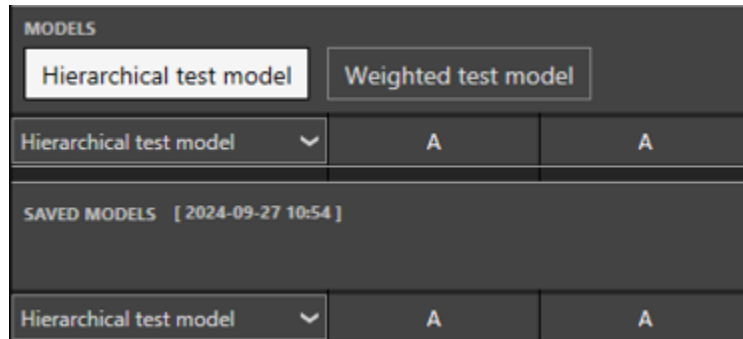


Figure 7.63 Hierarchical test model is now linked to a timelapse

When the embryo score model is saved, the date and time when it was saved will be written.

 When one embryo score model is selected and saved, another embryo score model cannot be saved to a timelapse.

 If there is a desire to add another embryo score model to a timelapse with linked models, the linked ones must be deleted before selecting multiple desired models and adding them at once.

Hierarchical score model

Near the created hierarchical score model, there is an arrow pointing down symbol. When it is pressed, all created conditional nodes will be listed.

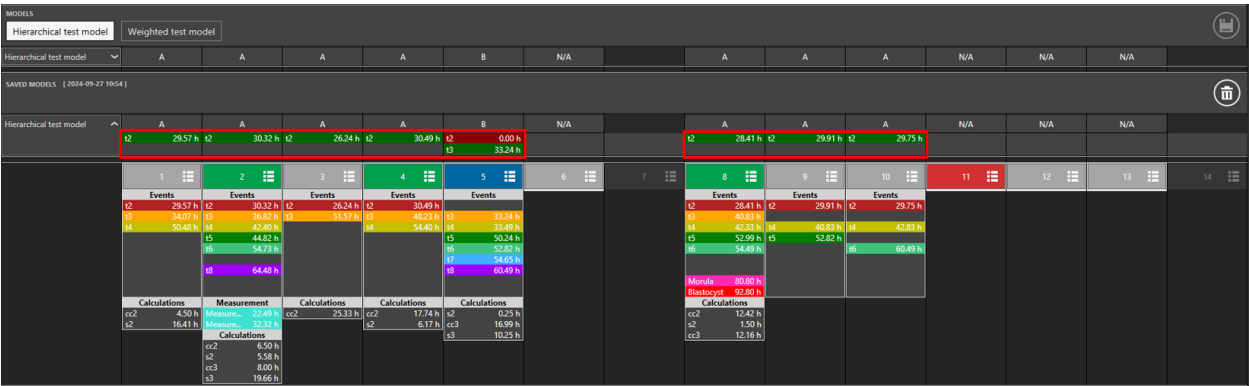


Figure 7.64 List of all conditional nodes that are created in the hierarchical score model

If there are no annotations for the wells, the “N/A” will be written according to the well number. If the conditional node result is “True”, it will be in green; if it is “False”, it will be in red, as seen in the Figure 7.64 above.

 The changes will not apply to a saved score model if the score model is modified in the “Settings” view.

Weighted score model

If there are no annotations for the wells, the “N/A” will be written according to the well number.

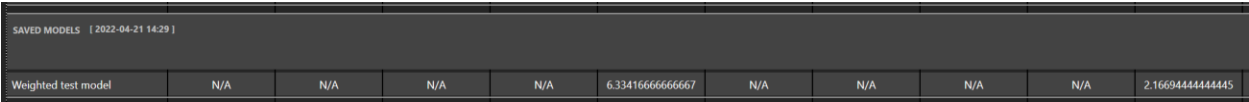


Figure 7.65 Results of all annotations with the linked weighted score model

As seen in the picture above, there are some irrational results. The user can modify the weighted score model formula in the “Settings” view to round the result (Fig. 7.66 shows how to round the result to 3 numbers after the comma).

Model Variables

Active ☒

Name
Weighted test model

Model type
Hierarchical Weighted

Score
roundn(events_t4 - events_t3, 3)

Figure 7.66 Modified weighted score model to show 3 numbers after the comma

As seen in the picture below, the saved model was not modified, but the “MODELS” list shows modified results with 3 numbers after the comma.

MODELS					
<div> <div>Hierarchical test model</div> <div>Weighted test model</div> </div>					
Weighted test model	N/A	N/A	N/A	N/A	6.334
SAVED MODELS [2022-04-21 14:29]					
Weighted test model	N/A	N/A	N/A	N/A	6.33416666666667

Figure 7.67 Results of all annotations with the linked weighted score model

The changes will not apply to a saved score model if the score model is modified in the “Settings”.

There are mathematical operations that the weighted score model supports:

1. **Basic Operations:**
 - Addition: “+”
 - Subtraction: “-”
 - Multiplication: “*”
 - Division: “/”
 - Modulo: “%”
 - Exponentiation: “^”
 - Negation: “!”
2. **Boolean Operations:**
 - Less than: “<”

- Less than or equal: "<=" or "≤"
- More than: ">"
- More than or equal: ">=" or "≥"
- Equal: "=="
- Not equal: "!=" or "≠"

A list of all standard functions that the weighted score model supports can be seen in Table 7.1.

Table 7.1 Standard Functions

Function	Arguments	Description
sin	sin(A1)	Sine
cos	cos(A1)	Cosine
asin	asin(A1)	Arcsine
acos	acos(A1)	Arccosine
tan	tan(A1)	Tangent
cot	cot(A1)	Cotangent
atan	atan(A1)	Arctangent
acot	acot(A1)	Arccotangent
loge	loge(A1)	Natural Logarithm
log10	log10(A1)	Common Logarithm
logn	logn(A1, A2)	Logarithm
sqrt	sqrt(A1)	Square Root
if	if(A1, A2, A3)	If Function
max	max(A1, ..., An)	Maximum
min	min(A1, ..., An)	Minimum
avg	avg(A1, ..., An)	Average
median	median(A1, ..., An)	Median
round	round(A1)	Round
roundn	round(A1,N)	Round number to N digits after comma
random	random()	Random

7.3.2.9 Export function

How to export a video:

When clicking the “Export” button, three options are listed. The user can select between making the video, the image or the Report. In this case, the user should press the “Video” button.

 Ensure to deselect any applied image presets before exporting images or videos of selected embryos. If an image preset remains applied, the exported video or image will include the applied image preset.

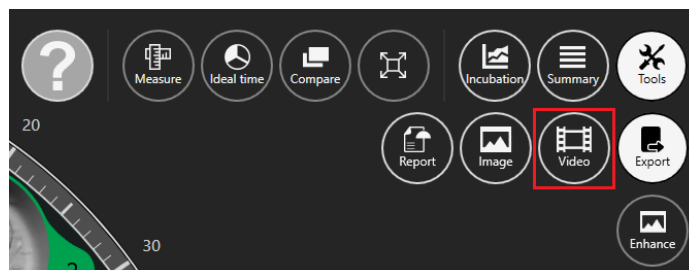


Figure 7.68 The “Export” option view

When the user selects the video option, the view changes to the video selection view. Here, a focal plane slider, the revolver view, the target directory window, the logo option and the status box can be seen.

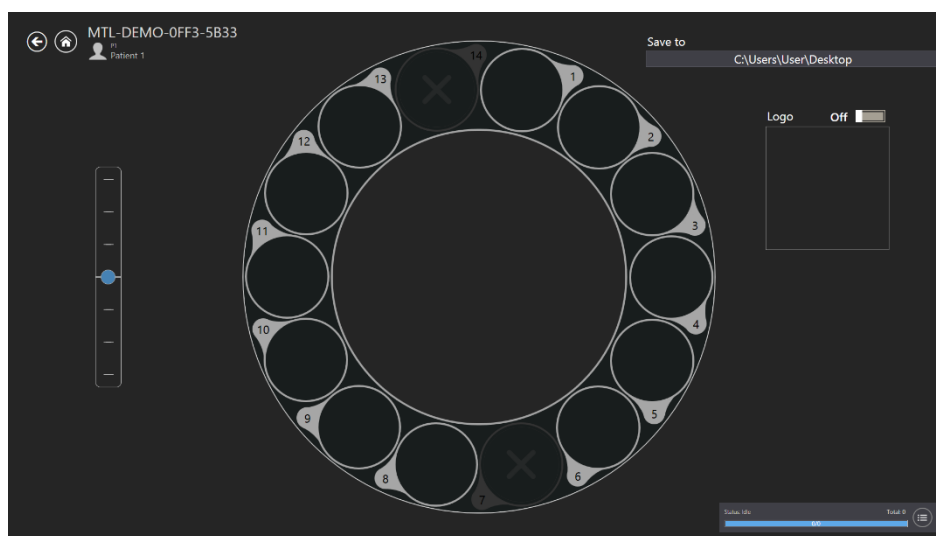


Figure 7.69 The video export view

Clicking the desired well number allows the user to select the timelapse video that they want to export. It is possible to select single or multiple wells for export. In the picture below, wells 1-3 are selected.

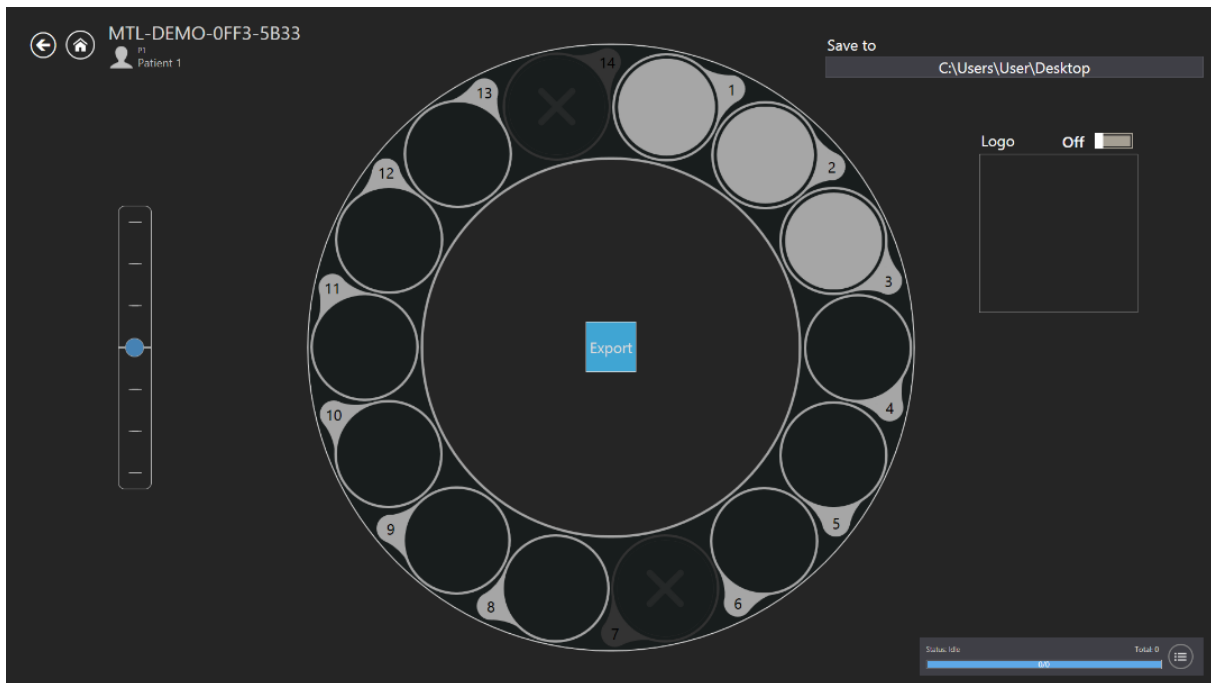


Figure 7.70 The video export view

Click on the “Save to” box in the top right corner to select the exact place where the exported video(s) will be saved. The resulting exported AVI file can be played in the Open-Source freeware VLC player (<http://www.videolan.org/vlc/>). Due to codec restrictions from Microsoft, Windows Media Player does not work.

A logo can be added to the movie by moving the slider to one. In the square below “Logo”, “Select image” will be displayed and only by clicking will it be possible to select a logo file.

After selecting the desired wells, click on the “Export” button. The exporting status will be updated on the bottom right of the screen.

 **It is possible to export a video in one focal plane at a time. To export in multiple focal planes, separate videos with the new focal plane selected beforehand must be exported each time.**

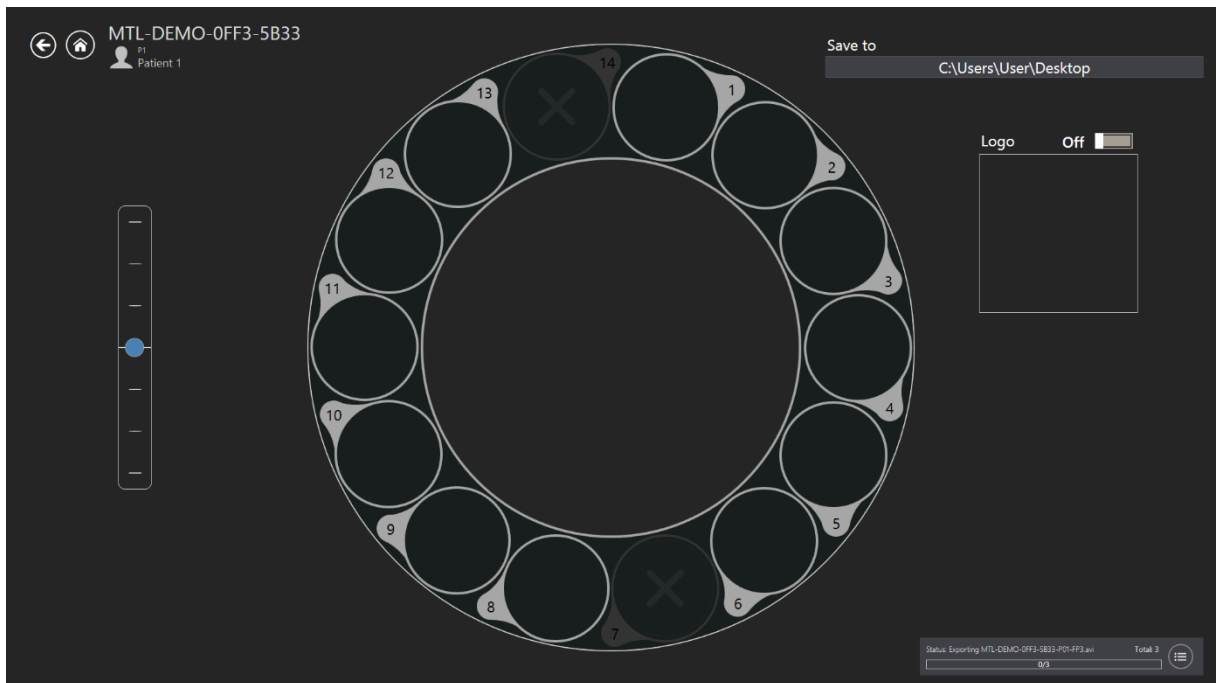


Figure 7.71 Exporting status

Click on the dedicated button to expand the exporting status box. This allows the user to observe the exporting status more precisely. Additionally, clicking on the dedicated buttons allows the user to end the exporting process prematurely for all or selected videos.

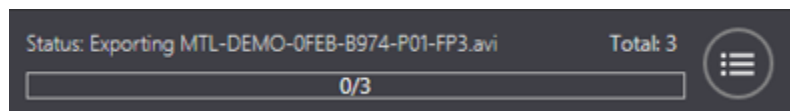


Figure 7.72 Exporting status box

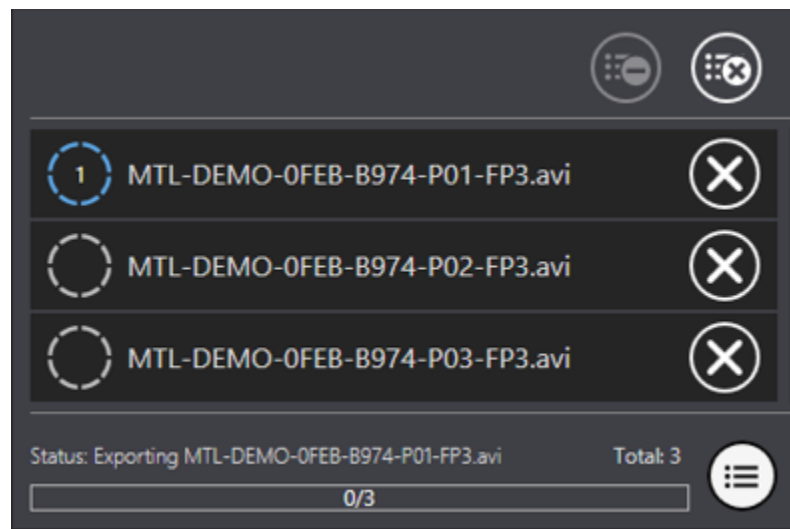


Figure 7.73 Exporting status box expanded

After the video(s) have been exported, the status will be updated. By clicking on the dedicated buttons, the user can navigate directly to the directory where the video(s) have been saved or delete all or selected videos.

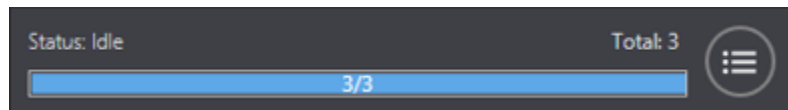


Figure 7.74 Exporting finished

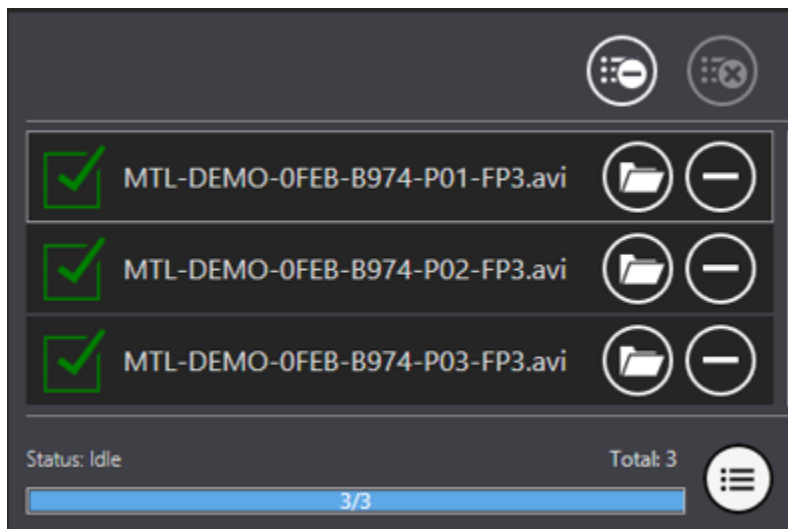


Figure 7.75 Exporting status box with exporting finished

👉 The photos for the videos inside the MIRI® TL family's multiroom IVF incubators are captured in a higher resolution. To improve the video viewing experience, the images are downscaled to 720p. Additionally, a timer is included in the lower right corner of the exported video for user convenience.

👉 Video exporting can occur in the background, allowing you to continue working while the videos are being exported.

👉 If the user decides to close the Viewer Software application while video exporting is in progress, a dialog box with a related notification will appear.

How to export an image:

When clicking the “Export” button, three options are listed. The user can select between making the video, the image or the Report. In this case, the user should press the “Image” button.

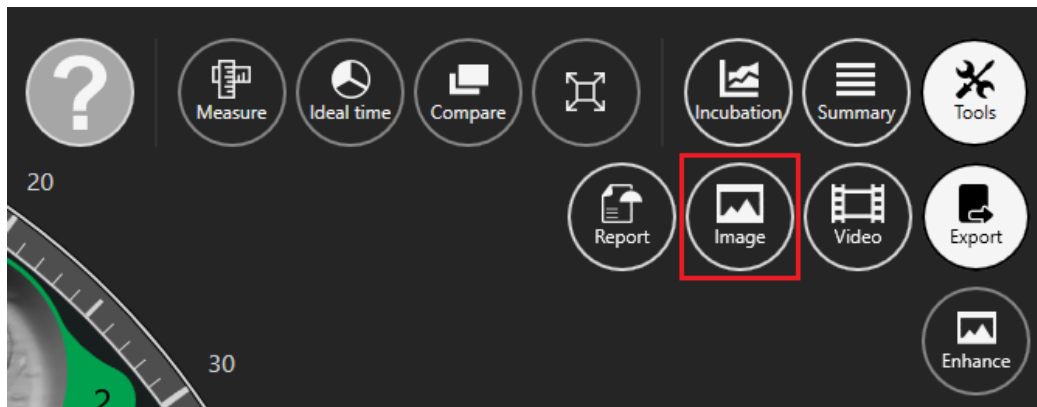


Figure 7.76 Selected image exportation button

When the desired image is selected and the “Image” button is pressed, it will open the window below.

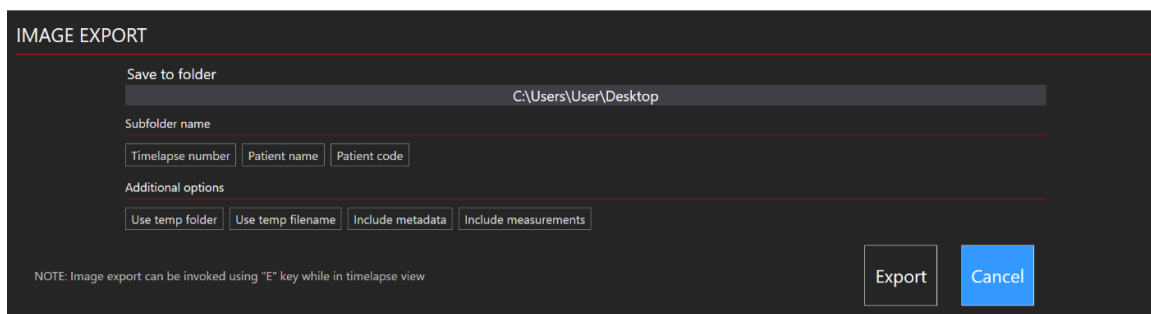


Figure 7.77 All options are inactive

The user can choose which information to include in the exported image.

It is possible to choose how the exported photos will be grouped. For example, if you select only the Timelapse number, a new directory, “MTL-DEMO-XXX-XXXX”, will be created, and photos will be placed in it. If nothing is selected, then all photos will be placed in the root directory.

There are additional options that can be included in the exported image: “Use temp folder”, “Use temp filename”, “Include metadata” and “Include measurements”.

Press on any of the options to include them in the exported file. Enabled options are colored in white.

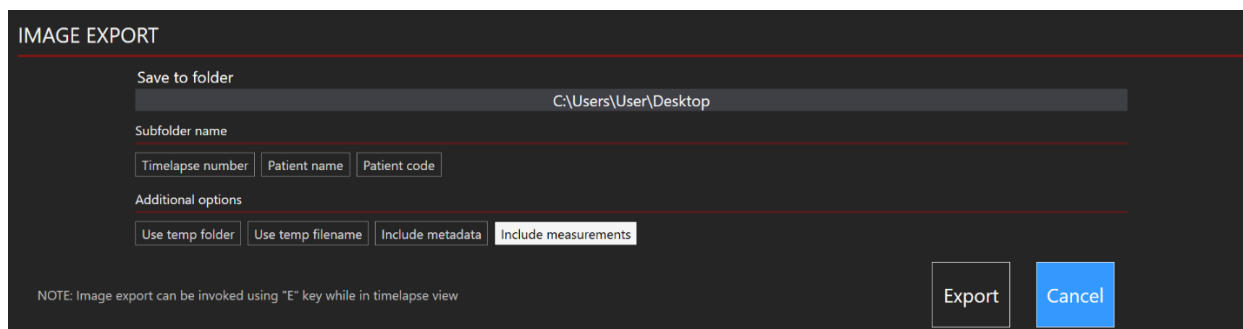


Figure 7.78 “Include measurements” option active

👉 As a default, “Include measurements” option is OFF, but after being included for the 1st time, it will be automatically included in other exported images.

👉 Notice that the image name does not change automatically, so be careful about overwriting the images!

👉 Image export can also be initiated using the “Control+E” shortcut on the keyboard (the exporting directory needs to be set beforehand). A confirmation will be displayed in the lower right corner of the screen.

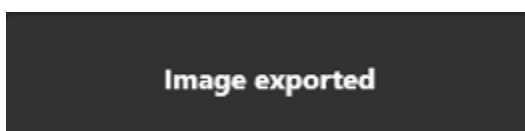


Figure 7.79 Exporting confirmation

How to export a report:

When clicking the “Export” button, three options are listed. The user can select between making the video, the image or the Report. In this case, the user should press the “Report” button.

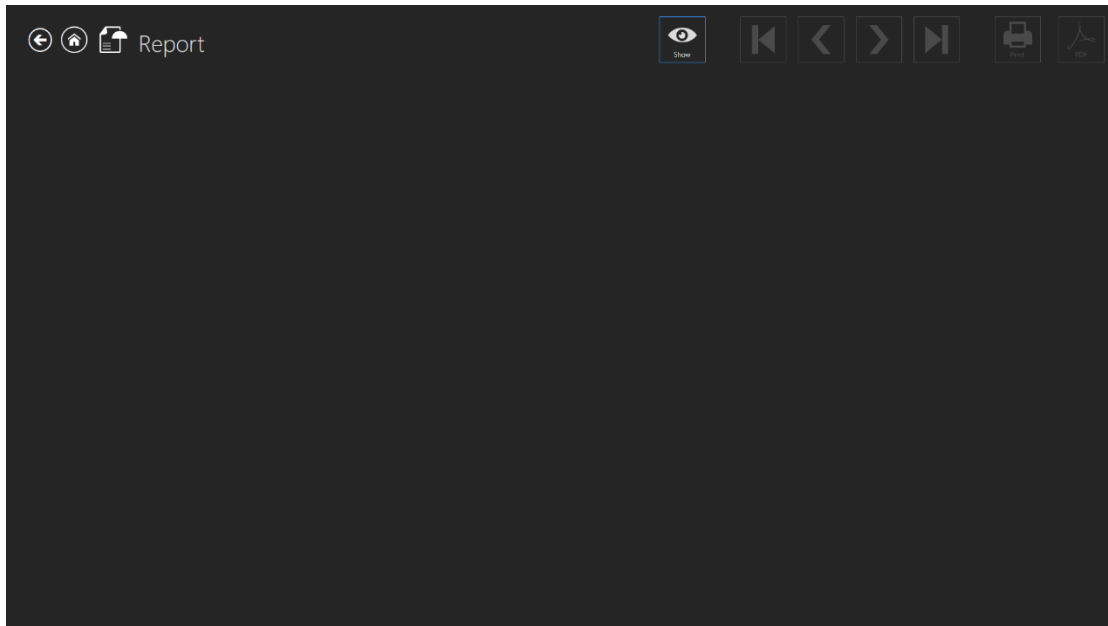


Figure 7.80 “Report” view

Clicking the “Show” button shows the report on the screen. Near the “Show” button, navigation buttons can be used to move between exported report pages. By clicking the first or fourth button, the user can navigate to the first and last report pages. By clicking the second and third buttons, the user can navigate one page per click. It is also possible to print or export a PDF file of the report.

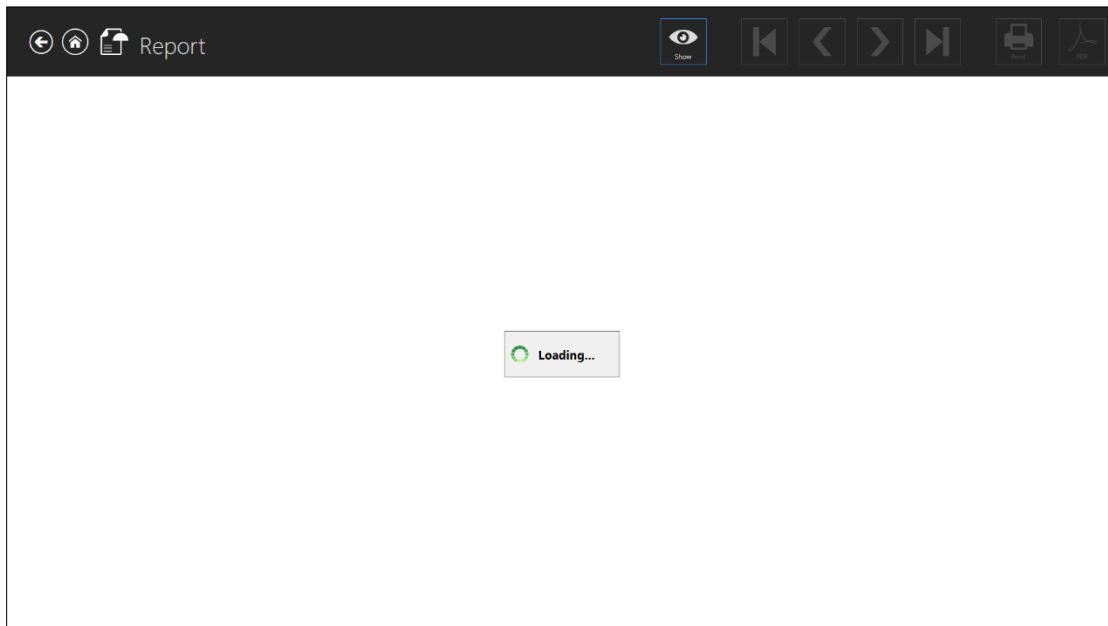


Figure 7.81 Report loading view

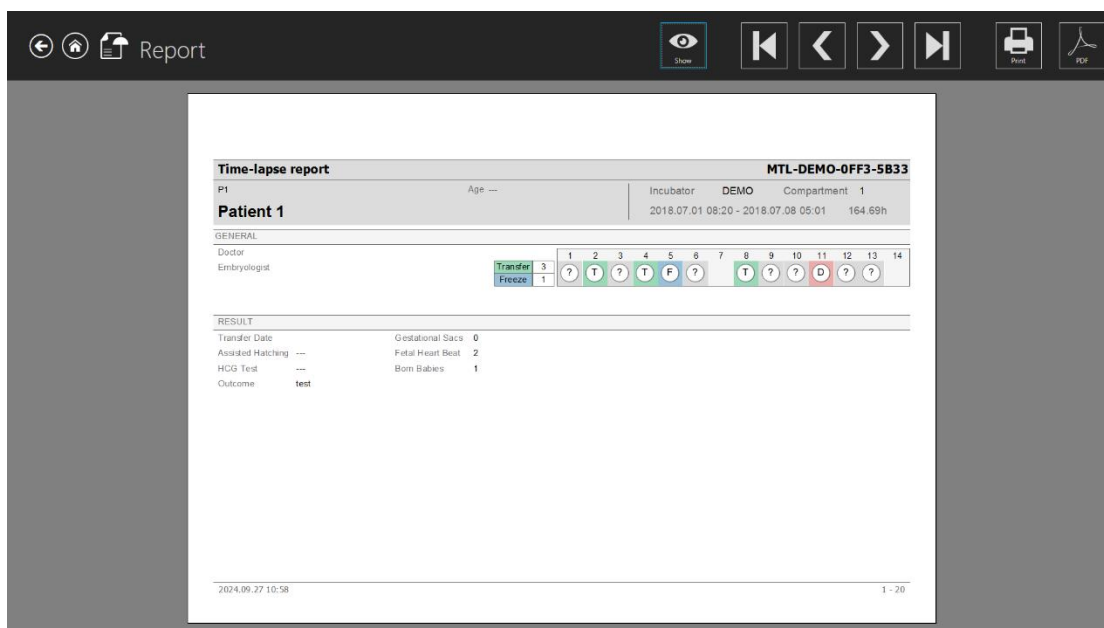


Figure 7.82 Timelapse report view (general page)

 The report may take a while to load.

The picture below shows all development images included when events were annotated. When the timelapse report is generated, images with measurements will be included automatically.

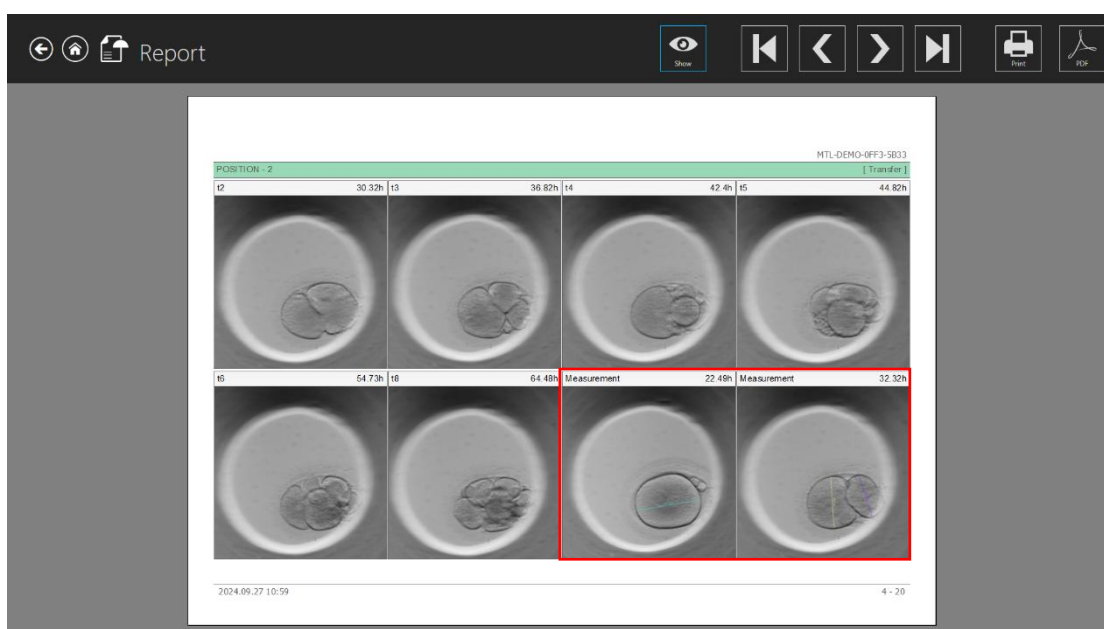


Figure 7.83 Images with measurement in a generated timelapse report

A table with all annotations and the related information is displayed in the picture below.

POSITION - 2		
MTL-DEMO-0FF3-S803		
ANNOTATION GROUP	NAME	TIME
Events	12	30.32h
	13	36.82h
	14	42.4h
	15	44.82h
	16	64.73h
	18	64.48h
Measurement	Measurement	22.49h
	Measurement	32.32h
Calculations	c2	6.5h
	c2	6.68h
	c3	8h
	s3	19.66h

Figure 7.84 Timelapse report view (annotations)

 All new additional information (i.e., outcomes, gestational sacs, etc.) is also included in the timelapse Report (Figure 7.84).

7.3.2.10 Image presets

A “Tools” button is located in the upper right corner of the timelapse view.

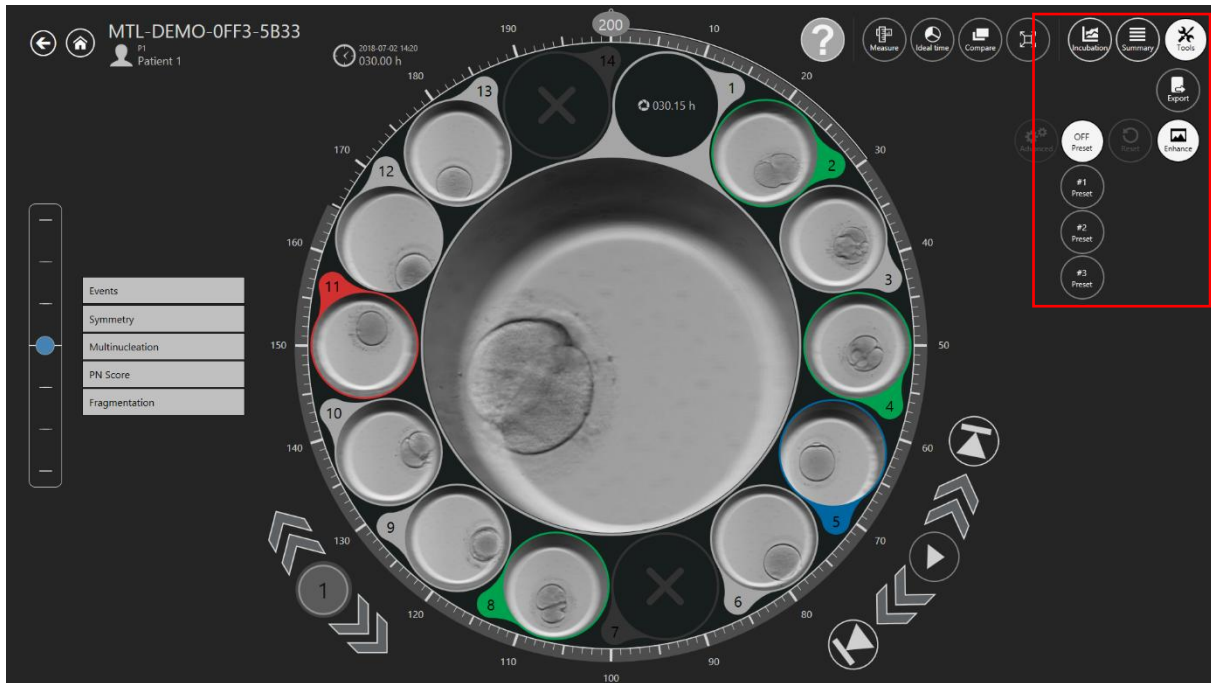


Figure 7.85 “Tools” button in the main MIRI® TL family’s multiroom IVF incubators screen

After pressing the “Tools” button, two additional options are listed: “Export” and “Enhance”.

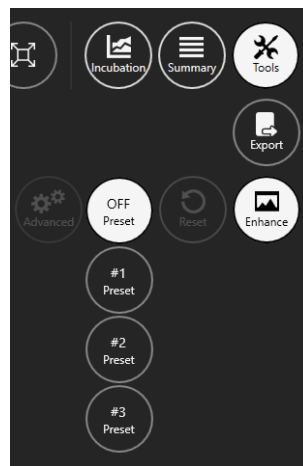


Figure 7.86 Image enhancement tool

By default, the image enhancement tool lists three image presets:

- **#1 Preset** – contrast enhance
- **#2 Preset** – edge enhance
- **#3 Preset** – bubble enhance

Any selected image preset will be applied to all timelapse images visible in timelapse and compare views.

Activated image preset also will be applied when exporting timelapse video, image and report.

 To disable the image enhancement feature, press the “OFF Preset” button.

 When MIRI® TL Viewer software launches, the image enhancement feature is always disabled.

 Ensure to deselect any applied image presets before exporting images or videos of selected embryos. If an image preset remains applied, the exported video or image will include the applied image preset.

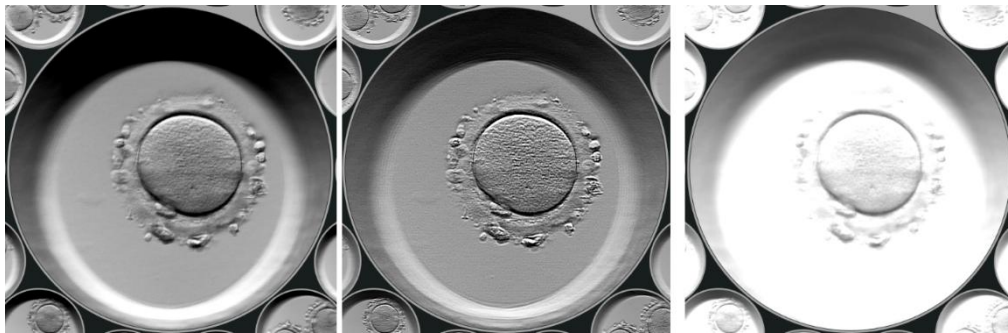


Figure 7.87 Active Preset #1, Preset #2 and Preset #3

7.3.2.10.1 Advanced settings

After pressing the desirable preset, an “Advanced” button will become active, allowing the user to access more advanced image enhancement settings.

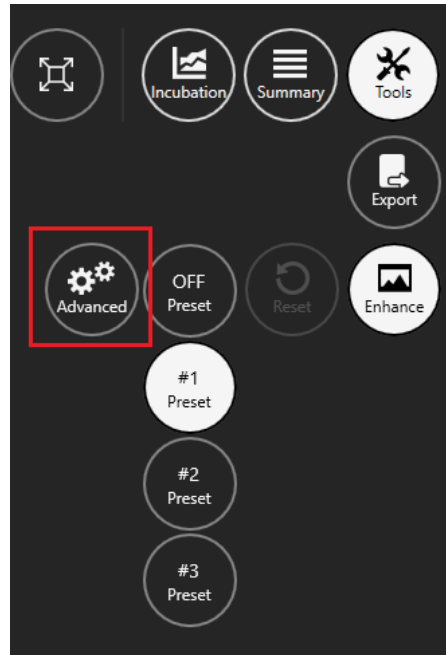


Figure 7.88 Advanced image enhancement settings

The advanced image enhancement settings will appear on the screen's left side.

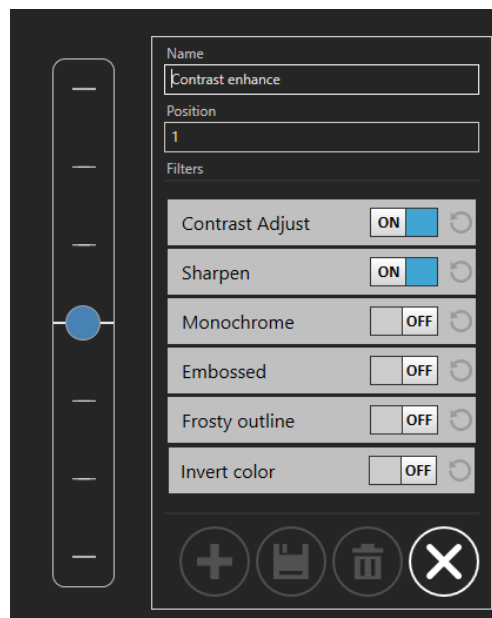


Figure 7.89 #1 Preset advanced settings

Each image enhancement setting contains an “ON/OFF” button which will immediately enable or disable image enhancement.



The #1, #2 and #3 default presets cannot be changed or modified.

When the “Contrast Adjust” button is pressed, two new options appear: “Brightness”, which can be adjusted from -1.00 to 1.00 and “Contrast”, which can be adjusted from 0.00 to 2.00.

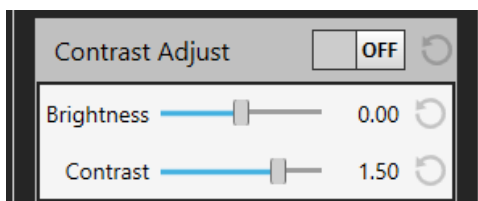


Figure 7.90 Contrast adjustment settings

When the “Sharpen” button is pressed, two new options appear: “Amount”, which can be adjusted from 0.00 to 2.00 and “Size”, where two options can be adjusted from 1 to 1000.

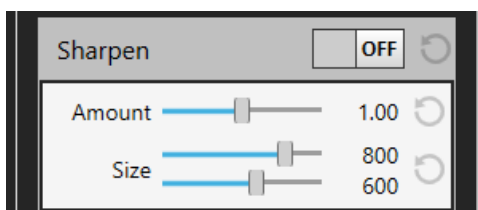


Figure 7.91 Sharpen settings

When the “Monochrome” button is pressed, the user has the option to apply a color filter. The user can choose from the available standard colors or make a custom color.

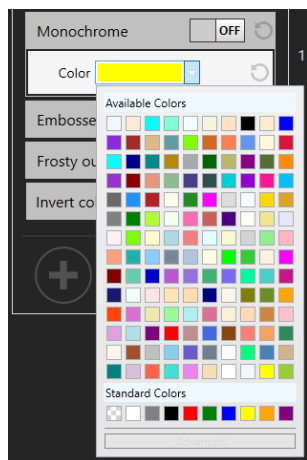


Figure 7.92 Standard color settings

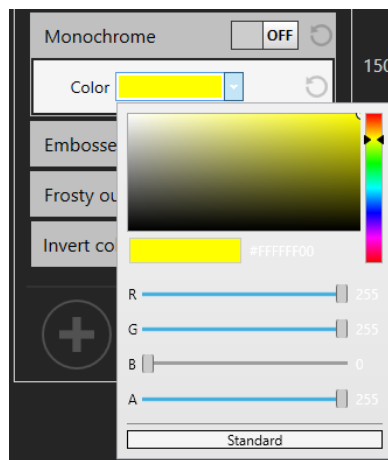


Figure 7.93 Advanced color settings

When the “Embossed” button is pressed, two new options appear: “Amount”, which can be adjusted from 0.000 to 1.000 and “Width”, which can be adjusted from 0.000 to 0.010.

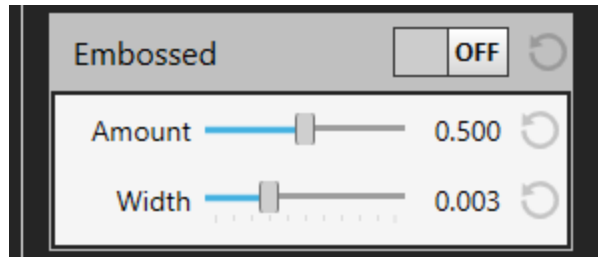


Figure 7.94 Embossed settings

When the “Frosty outline” button is pressed, two new options appear: “Width”, which can be adjusted from 150 to 650 and “Height”, which can be adjusted from 150 to 400.

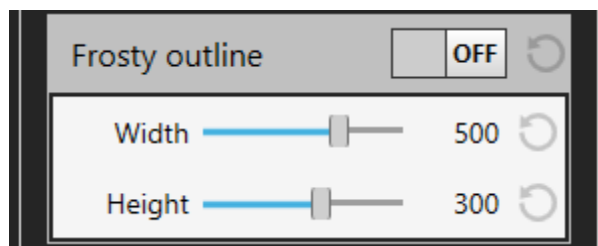


Figure 7.95 Frosty outline settings

The user can also use an “Invert color” filter. However, it does not have any additional settings.



Figure 7.96 Invert color settings

7.3.2.10.2 Image preset creation

When creating a new image preset, the user can create a name and apply a position, by which the preset will be shown in the created image preset list.

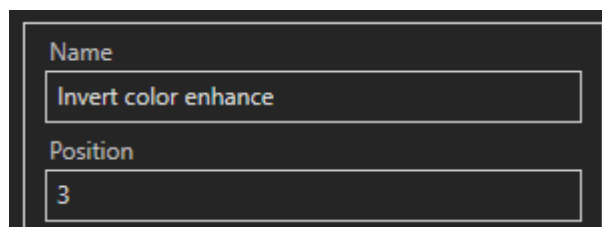


Figure 7.97 Creation of a new image preset name and position



When creating a new image preset, the “Position” shouldn’t be modified. After adding a preset it will be automatically updated.

To apply the “Invert color” filter, press the “ON/OFF” button.

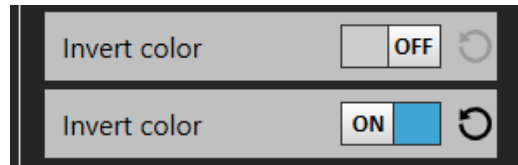


Figure 7.98 “ON/OFF” button

After applying the desired image enhancement settings, the user can add a new image preset by pressing the “Add new preset” button.

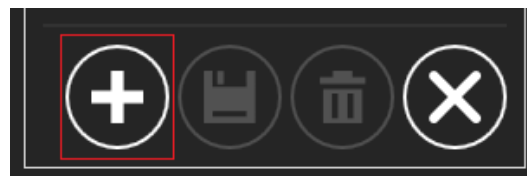


Figure 7.99 “Add new preset” button

After the new image preset is saved, it will appear on the left side of the screen, below the default image presets. Hover the mouse on the newly created image preset icon to see the full name.

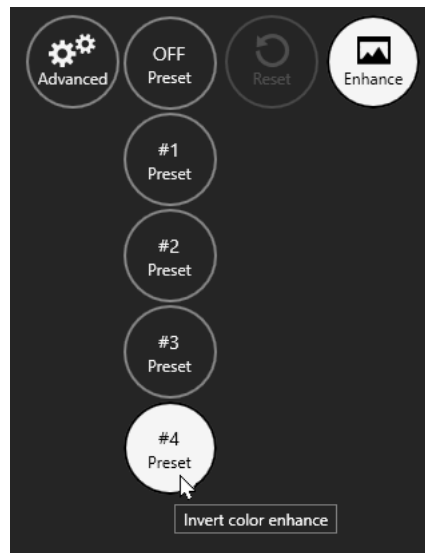


Figure 7.100 Created image preset name

If the user decides to modify the existing image preset after applying other image enhancement settings, it can be done by pressing the “Save changes” button.



Figure 7.101 “Save changes” button

If the user wants to create another image preset after applying other image enhancement settings, it can be done by pressing the “Add new preset” button, as described in Figure 7.99.

If the user wants to delete created image preset, it can be done by pressing the “Delete preset” button.



Figure 7.102 “Delete preset” button

To exit the advanced image enhancement settings, press the “Cancel” button.



Figure 7.103 “Cancel” button

The user can reset the modified image enhancement settings by pressing the “↺” button near the “ON/OFF” button.

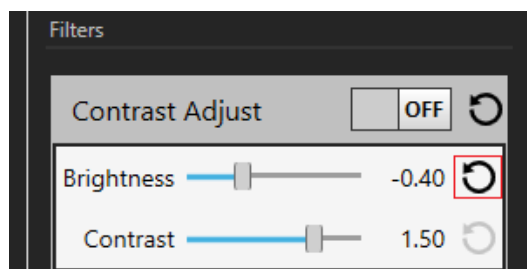


Figure 7.104 Reset the modified image enhancement settings button

The “Reset” button is also near the “Enhance” button.

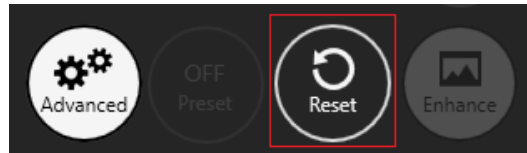


Figure 7.105 “Reset” button

👉 The total number of image presets that can be applied to the timelapses is 11 (including 3 default image presets).

👉 Ensure to deselect any applied image presets before exporting images or videos of selected embryos. If an image preset remains applied, the exported video or image will include the applied image preset.



Figure 7.106 Maximum number of image presets

7.4 Patients

7.4.1 Patient list

In the patient's view, a list of the patients entered into the system can be seen.

Code #	Name	Diagnosis	Last Outcome	Created
P2	Patient 2			2024-09-17 12:29
P1	Patient 1		test	2015-05-10 12:00

Figure 7.107 Patient list view

There is now a possibility to filter patients by their last treatment outcome. The option is located at the top of the screen in the Patient list view.

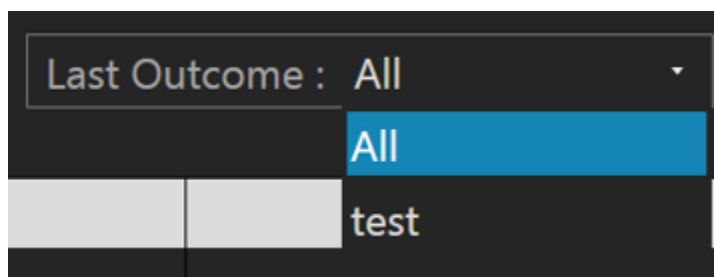


Figure 7.108 Last outcome filtration

The patient treatment list also has a “Last outcome” column, as shown in the picture below.

Treatment #	Patient Name	Protocol	Last Outcome	Created
1	Patient 10			2021-02-11 14:19
2	Patient 10		not pregnant	2021-02-11 14:20
3	Patient 10		pregnant	2021-02-11 14:20

Figure 7.109 Patient treatment outcome filtration

There is a search function in the top right corner of the patient's list view, where the patient's name or code can be entered to find the correct patient.

The “Reset” button will reset all selected filters.

The user can generate a patient's annotation file by pressing the “Report” button at the top right corner of the patient's list view.

The patient can be deleted by pressing on the desired patient and pressing the “Delete” button at the top right corner of the patient list view. A new window will pop up, informing the user that all selected patient data will be deleted.

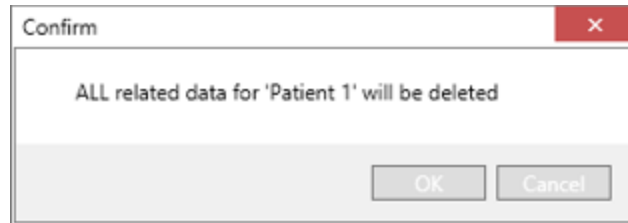


Figure 7.110 Confirmation window that all selected patient's data will be deleted

There will be a big “Timelapses” button to the right under the particular patient.

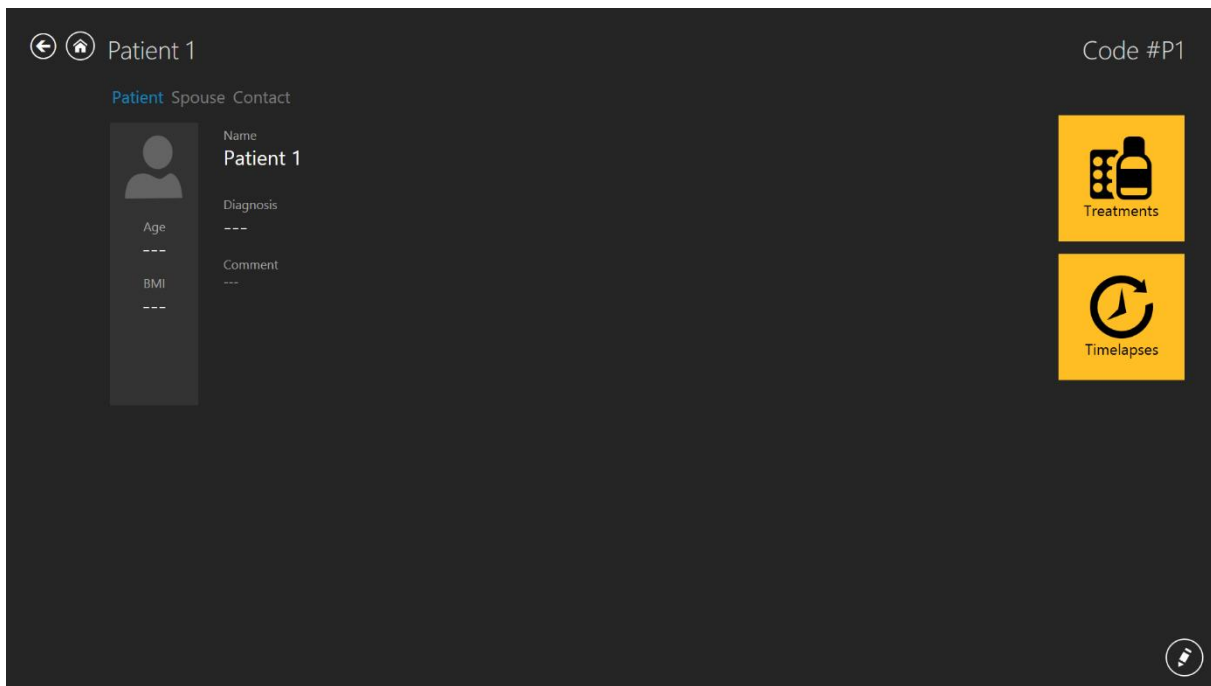
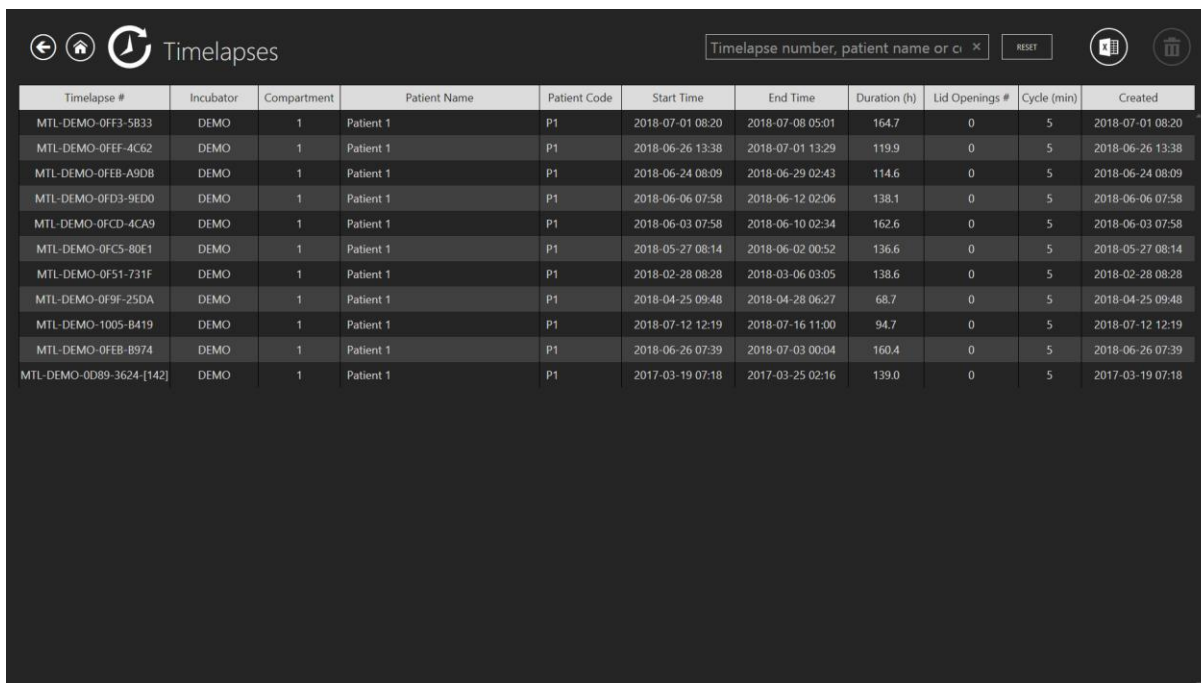


Figure 7.111 Selected patient view

Pressing on the “Timelapses” button will open the timelapses list for the selected patient.



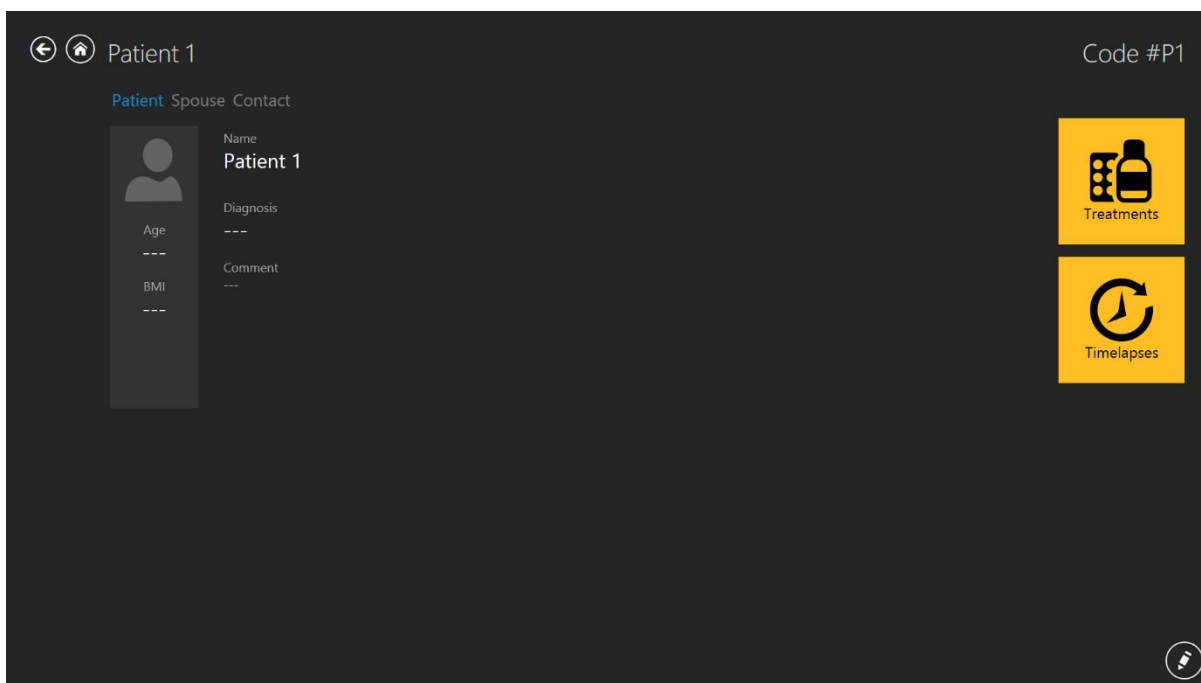
The screenshot shows the 'Timelapses' application window. At the top, there is a search bar with the text 'Timelapse number, patient name or c' and a 'RESET' button. Below the search bar is a table with 11 columns: Timelapse #, Incubator, Compartment, Patient Name, Patient Code, Start Time, End Time, Duration (h), Lid Openings #, Cycle (min), and Created. The table contains 10 rows of data for Patient 1, with Patient Code P1. The data is as follows:

Timelapse #	Incubator	Compartment	Patient Name	Patient Code	Start Time	End Time	Duration (h)	Lid Openings #	Cycle (min)	Created
MTL-DEMO-0FF3-5B33	DEMO	1	Patient 1	P1	2018-07-01 08:20	2018-07-08 05:01	164.7	0	5	2018-07-01 08:20
MTL-DEMO-0FEF-4C62	DEMO	1	Patient 1	P1	2018-06-26 13:38	2018-07-01 13:29	119.9	0	5	2018-06-26 13:38
MTL-DEMO-0FEB-A9DB	DEMO	1	Patient 1	P1	2018-06-24 08:09	2018-06-29 02:43	114.6	0	5	2018-06-24 08:09
MTL-DEMO-0FD3-9ED0	DEMO	1	Patient 1	P1	2018-06-06 07:58	2018-06-12 02:06	138.1	0	5	2018-06-06 07:58
MTL-DEMO-0FCD-4CA9	DEMO	1	Patient 1	P1	2018-06-03 07:58	2018-06-10 02:34	162.6	0	5	2018-06-03 07:58
MTL-DEMO-0FC5-80E1	DEMO	1	Patient 1	P1	2018-05-27 08:14	2018-06-02 00:52	136.6	0	5	2018-05-27 08:14
MTL-DEMO-0F51-731F	DEMO	1	Patient 1	P1	2018-02-28 08:28	2018-03-06 03:05	138.6	0	5	2018-02-28 08:28
MTL-DEMO-0F9F-25DA	DEMO	1	Patient 1	P1	2018-04-25 09:48	2018-04-28 06:27	68.7	0	5	2018-04-25 09:48
MTL-DEMO-1005-B419	DEMO	1	Patient 1	P1	2018-07-12 12:19	2018-07-16 11:00	94.7	0	5	2018-07-12 12:19
MTL-DEMO-0FEB-8974	DEMO	1	Patient 1	P1	2018-06-26 07:39	2018-07-03 00:04	160.4	0	5	2018-06-26 07:39
MTL-DEMO-0D89-3624 [142]	DEMO	1	Patient 1	P1	2017-03-19 07:18	2017-03-25 02:16	139.0	0	5	2017-03-19 07:18

Figure 7.112 Selected patient timelapses view

7.4.2 Patient view

Double-clicking on the desired patient will open the selected patient view.



The screenshot shows the 'Patient 1' view. At the top, there is a header with 'Patient 1' and 'Code #P1'. Below the header, there is a section for patient information with a profile icon and fields for Name, Age, BMI, Diagnosis, and Comment. The patient's name is 'Patient 1'. To the right of the patient information, there are two large yellow buttons: 'Treatments' and 'Timelapses'. The 'Timelapses' button is highlighted with a circular icon.

Figure 7.113 Selected patient view

The “Edit” button is located at the bottom right of the screen.

The specific patient view has database information about the patient. All the data can be edited here or added if left blank when the patient data was created. Add and edit data by pressing the “Pencil” button in the lower right corner. The user must save (“Save” button appears when information has been added) for any changes to be stored.

The “Plus” button in the top right corner of the patient list view lets the user add a new patient. When it is pressed, a new view opens up:

Figure 7.114 New patient creation window

Various information about the patient can be typed in:

- Code # (identifier number – if left blank, the system will assign a unique code)
- Name (must be provided)
- Birthdate (user calendar function to set the date)
- Age (is calculated)
- Diagnosis
- Comment

The birthdate is entered by using the calendar function that opens up when pressed.

Navigation icons: back, home, add

Code #

Patient Spouse Contact

Code #

Name

Birth Date: Select a date (27) Age: ---

September 2024

Su	Mo	Tu	We	Th	Fr	Sa
25	26	27	28	29	30	31
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	1	2	3	4	5

Save icon

Figure 7.115 Birthdate input

Most of the information in the database is voluntary to enter, except for the patient’s name. The system will warn if the necessary information has not been entered.

Navigation icons: back, home, add

Code #

Patient Spouse Contact

Code #

Name: The Name field is required

Birth Date: Select a date (27) Age: ---

Diagnosis

Comment

Correct errors

Save icon

Figure 7.116 Warning information

The “Save” button in the lower right corner stores the provided information.

Pressing on the “Spouse” brings up a view where data for the spouse can be entered.

Figure 7.117 Information about spouse window

The name and birthdate can be entered. The save button in the lower right corner stores the information.

Pressing on the “Contact” brings up a view where detailed contact information can be entered.

Figure 7.118 Contact information window

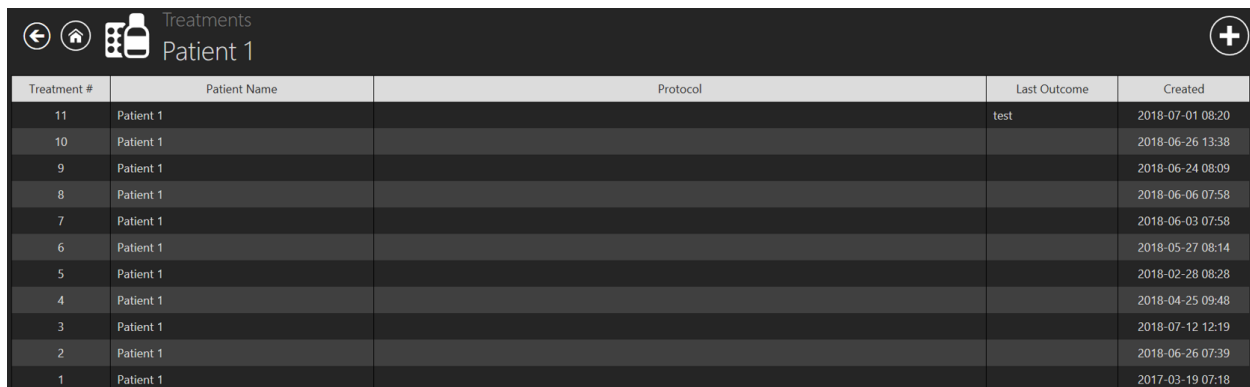
Various phone numbers, e-mail and addresses can be entered. The save button in the lower right corner stores the information.

When a patient has been added to the database, the information will be available on the list in the main patient's view.

7.4.3 Treatment view

To generate a treatment for the patient, the user needs to open the Patient view (for more information, please refer to the “7.4.2 Patient view” section of the User Manual).

There will be a big “Treatment” button to the right under the particular patient. It opens up the treatment view that contains an overview list of the current or previous treatments for the patient and lets the user add a new treatment.



Treatment #	Patient Name	Protocol	Last Outcome	Created
11	Patient 1		test	2018-07-01 08:20
10	Patient 1			2018-06-26 13:38
9	Patient 1			2018-06-24 08:09
8	Patient 1			2018-06-06 07:58
7	Patient 1			2018-06-03 07:58
6	Patient 1			2018-05-27 08:14
5	Patient 1			2018-02-28 08:28
4	Patient 1			2018-04-25 09:48
3	Patient 1			2018-07-12 12:19
2	Patient 1			2018-06-26 07:39
1	Patient 1			2017-03-19 07:18

Figure 7.119 Selected patient treatment view

Pressing the “Plus” button opens up the new treatment window.

Figure 7.120 New treatment window

The “Plus” button in the lower panel opens up more possibilities for entering specific information about the patient's treatments.

The “General” section shows the doctor, embryologist and a comment field. All of it is optional information. However, be sure to save if the information is entered.

The first “Plus” button will add the “Medication” section.

The screenshot displays the 'Medication' section of the treatment creation view for 'Patient 1'. The interface includes a top navigation bar with a back arrow, a home icon, and a treatment icon. The 'Medication' section is highlighted in blue. It contains the following fields:

- Medication Protocol:** A dropdown menu with a close button (x).
- Medication Brand:** A dropdown menu with a close button (x).
- Oocyte Triggering:** A dropdown menu with a close button (x).
- FSH Dose (IU):** A text input field with a close button (x).
- Comment:** A large text area with a close button (x).

At the bottom of the screen, there is a navigation bar with five buttons: Oocytes (plus icon), Culture (plus icon), Insemination (plus icon), Result (plus icon), and Remove (minus icon). On the far right of the navigation bar are two additional icons: a close button (x) and a save button (floppy disk).

Figure 7.121 Added “Medication” section

In this section, the information about the medication can be entered:

- Medication Protocol
- Medication Brand
- Oocyte Triggering
- FSH dose
- Comments (free text field)

At the bottom of the treatment creation view, the rest of the treatment information sections are still listed. Only the opened “Medication” section has been removed from the list of possible additions since the view is currently open. Now it can be seen under the patient name (in this instance it is “Patient 1”) in blue.

Save the information that has been entered under the “Medication” section by pressing the “Save” button.

The additional field can be deleted by pressing the “Remove” button. By doing this, the “Medication” option goes back to the bottom left of the screen.

Pressing the “Plus” button under “Oocytes” opens the oocytes section.

Treatment Patient 1 # 0

General Medication **Oocytes**

Oocyte Source x

Oocyte Quality x

Comment x

Retrieval Date

Enable

Retrieved	Mature	Immature
+ -	+ -	+ -

+ Culture
 + Insemination
 + Result
 - Remove
 X
 Save

Figure 7.122 Added “Oocytes” section

In this section, the information about the oocytes can be entered:

- Oocyte Source
- Oocyte Quality
- Retrieval date
- The field for noting down the split between retrieved, mature and immature
- Comment (free text field)

Save the information that has been entered under the “Oocytes” section by pressing the “Save” button.

Again, the “Plus” button list at the bottom is reduced with now both “Medication” and “Oocytes”. Note that the sections under treatment at the top show how deep into the sections layers the user has navigated. Here it shows “General” (1st section), “Medication” (2nd section), “Oocytes” (colored blue – meaning active view).

Pressing the “Plus” button under “Culture” opens the culture section.

The screenshot displays the 'Culture' section of the MIRI TL Viewer Software. At the top, there is a header bar with navigation icons (back, home, list) and a title 'Treatment Patient 1' with a '# 0' indicator. Below the header, a tab bar shows 'General', 'Medication', 'Oocytes', and 'Culture' (highlighted in blue). The main content area contains two input fields: 'Culture Type' with a dropdown menu and a close button (x), and 'Comment' with a text area and a close button (x). At the bottom, there is a navigation bar with three buttons: 'Insemination' (plus icon), 'Result' (plus icon), and 'Remove' (minus icon). On the far right of the bottom bar are two additional icons: a close button (x) and a save button (floppy disk).

Figure 7.123 Added “Culture” section

In this section, the information about the culture can be entered:

- Culture type
- Comment (free text field)

Save the information that has been entered under the “Culture” section by pressing the “Save” button.

Again, the list of the “Plus” button is reduced and the section list under treatments is increased with the now open “Culture” section.

Pressing the “Plus” button under “Insemination” opens the insemination section.

Figure 7.124 Added “Insemination” section

In this section, the information about insemination can be entered:

- Insemination Type (IVF, ICSI)
- Date
- Comment (free text field)

 **The insemination time must be entered correctly for any subsequent meaningful analysis of the timelapse data. Division timings are calculated and registered according to the insemination time as the starting point. If no time is entered, the system will use it when the timelapse is started as time zero. It can be useful if culturing oocytes as naturally, no insemination time would exist at this time point.**

Save the information that has been entered under the “Insemination” section by pressing the “Save” button.

The last remaining “Plus” button under the “Result” opens the results section.

The screenshot shows the 'Result' section of the MIRI TL Viewer Software. At the top, there are navigation icons and a title bar with 'Treatment Patient 1' and a patient number '# 0'. Below the title bar, there are tabs for 'General', 'Medication', 'Oocytes', 'Culture', 'Insemination', and 'Result'. The 'Result' tab is selected. The main area contains several input fields and buttons: 'Transfer Date' with an 'Enable' button, 'Transfer Comment' with a text area and a close button, 'Assisted Hatching' with an 'Unset' button, 'HCG Test' with an 'Unset' button, 'Gestational Sacs' with a '+' button, 'Fetal Heart Beat' with a '+' button, 'Born Babies' with a '+' button, and 'Outcome' with a text field and a close button. At the bottom, there is a 'Remove' button and a close button.

Figure 7.125 Added “Result” section

In this section, the information about the result can be entered:

- Transfer Date
- Transfer Comment (free text field)
- Assisted Hatching (unset – no – yes)
- HCG Test (unset – negative – positive)
- Gestational Sacs (from 0 to 5)
- Fetal Heart Beat (from 0 to 5)
- Born Babies (from 0 to 5)
- Outcome (free text field)

Save the information that has been entered under the “Result” section by pressing the “Save” button.

The results are set in by clicking the round button until it shows the correct result.

The user can delete anything they write in an “open text” field, such as “Outcome,” “Patient name or code,” “Transfer comment,” etc.

It can be done by pressing the “X” button marked red in the picture below.

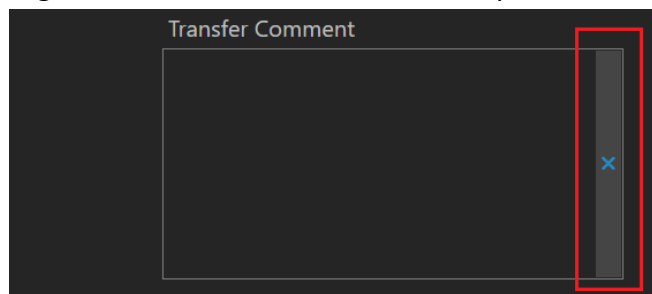


Figure 7.126 “Clear” button

7.4.4 Timelapse creation view

Under the treatment view for the specific patient, it is possible to start a new timelapse.

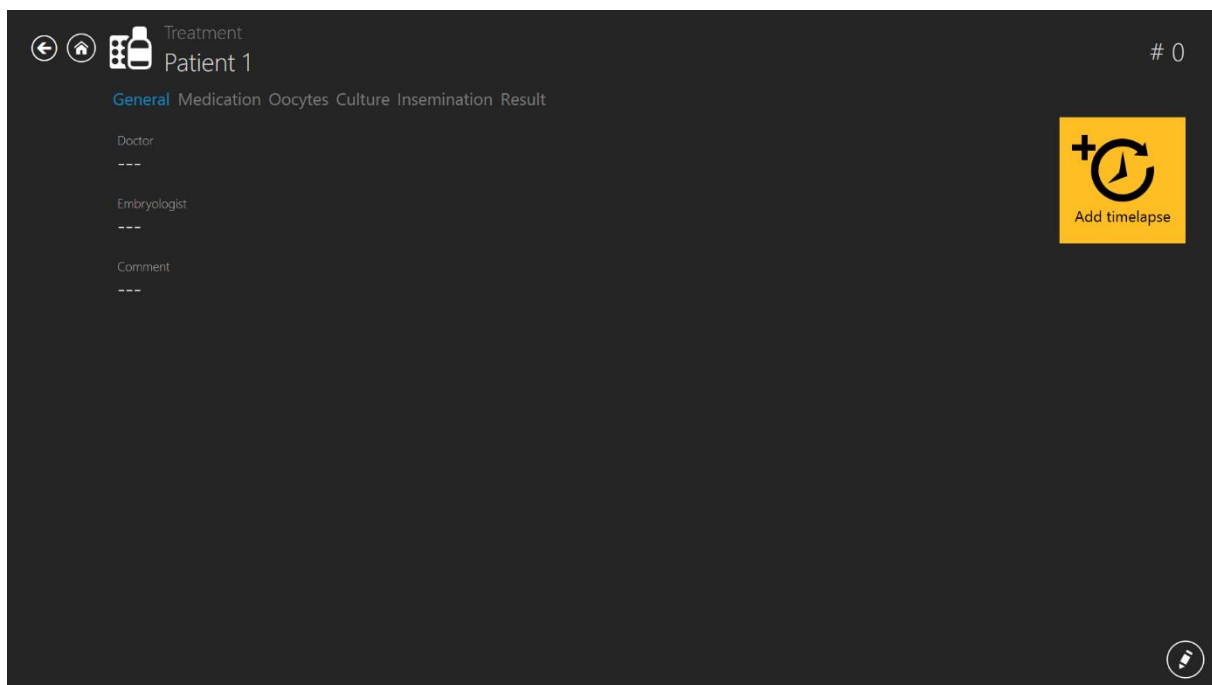


Figure 7.127 “Add timelapse” button under the specific patient treatment

By pressing the “Add timelapse” button, a new window will open. The user must select which device the timelapse is sent to.

If there are incubators that are disabled in the “Incubator” view, they will not be visible in the “Select incubator” window below.

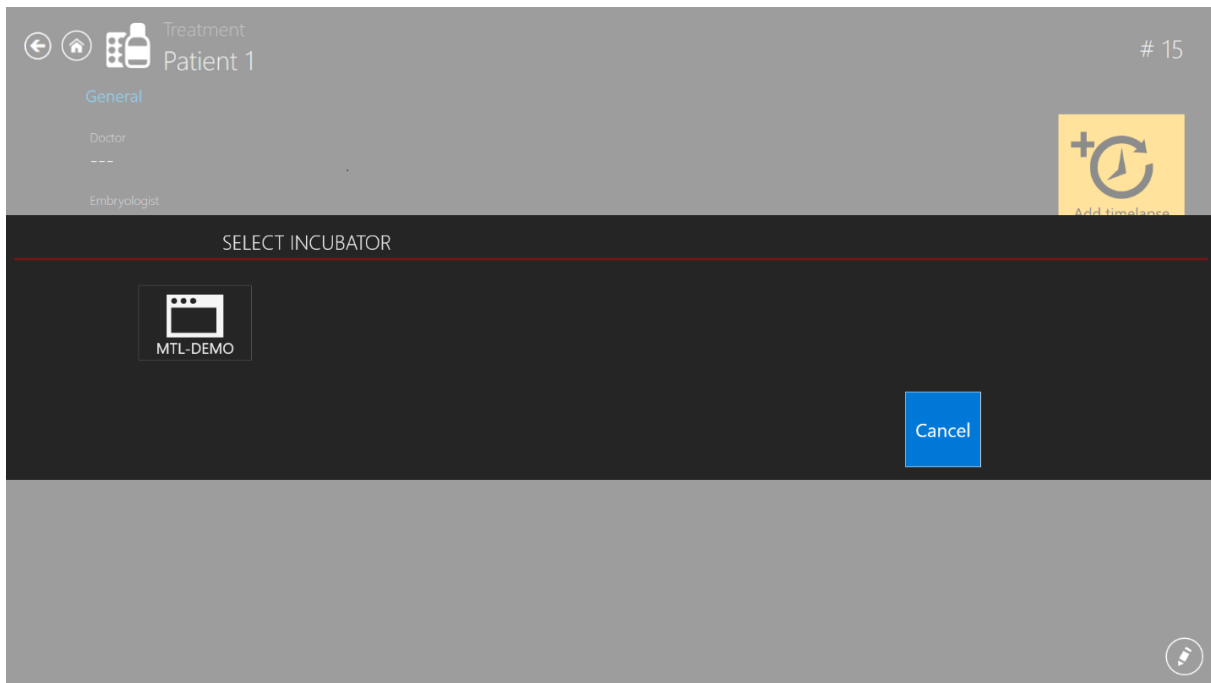


Figure 7.128 Select the device in which timelapse is sent

 One treatment can only have one timelapse. If the user wants to add more timelapses for the patient, a new treatment must be added.

 A timelapse must first be made on the TL Viewer and be sent to the MIRI® TL6 and MIRI® TL12 multiroom IVF incubator to show up on the list of available patients on the MIRI® TL6 and MIRI® TL12 multiroom IVF incubator. A timelapse cannot be started in any other way.

 For instructions on enabling/disabling incubators, please refer to the “7.5 Incubator list” section of the User Manual.

If the timelapse has been made, the treatment page will look like the image below, and by pressing the “Timelapse” button, Timelapse view will be shown:



Figure 7.129 Treatment view when the timelapse has been made

By pressing the “Timelapse” button, the Timelapse view will be shown.

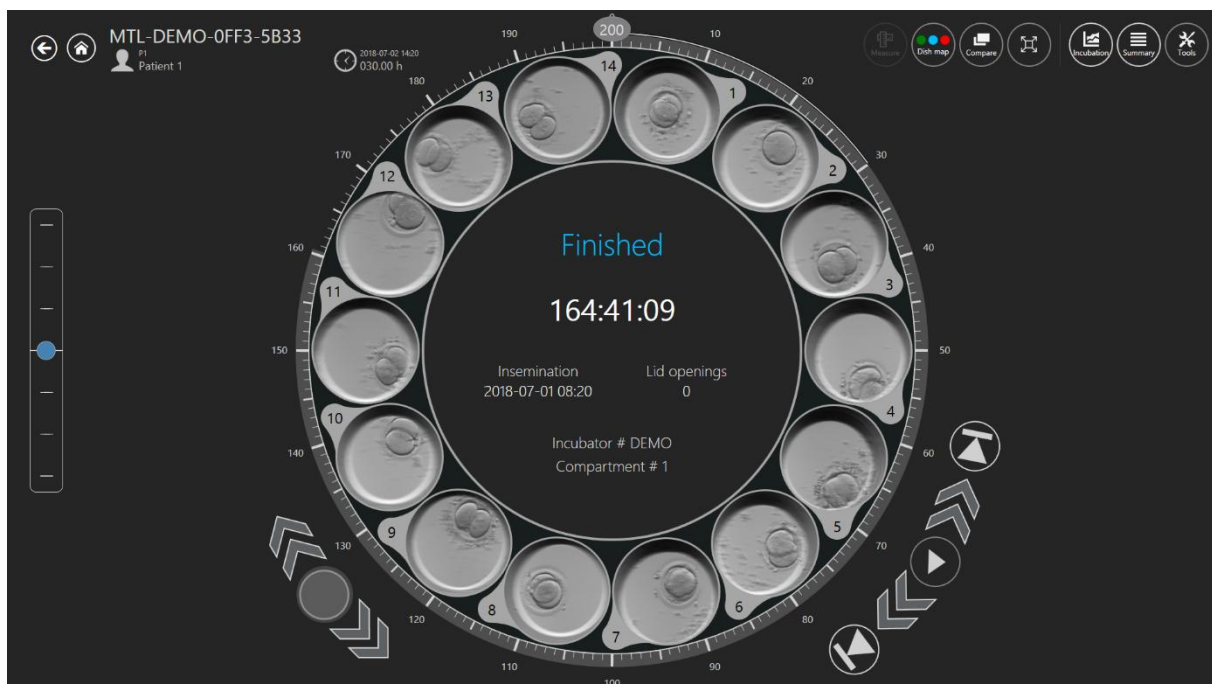


Figure 7.130 The timelapse view of a specific patient

7.5 Incubator list

Pressing on an “Incubator” button in the main view will open a new window where the user can see all MIRI® TL family’s multiroom IVF incubators that have ever been connected to MIRI® TL family’s multiroom IVF incubators Viewer software.

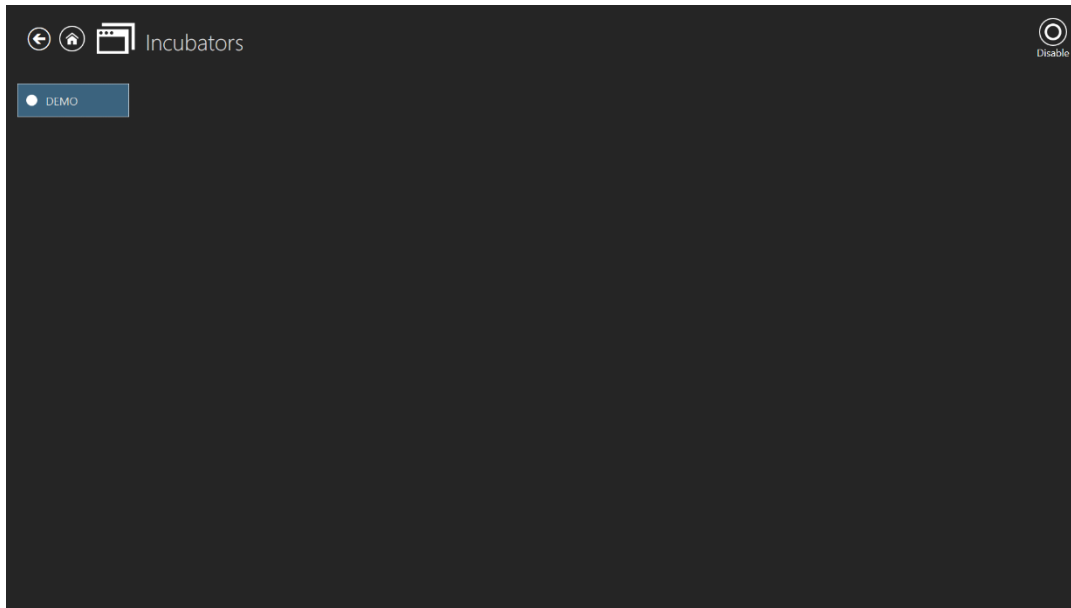


Figure 7.131 “DEMO” incubator is enabled

By pressing the “Disable” button in the top right corner, the user can disable the marked incubator. It will no longer be available for selection when creating a timelapse.

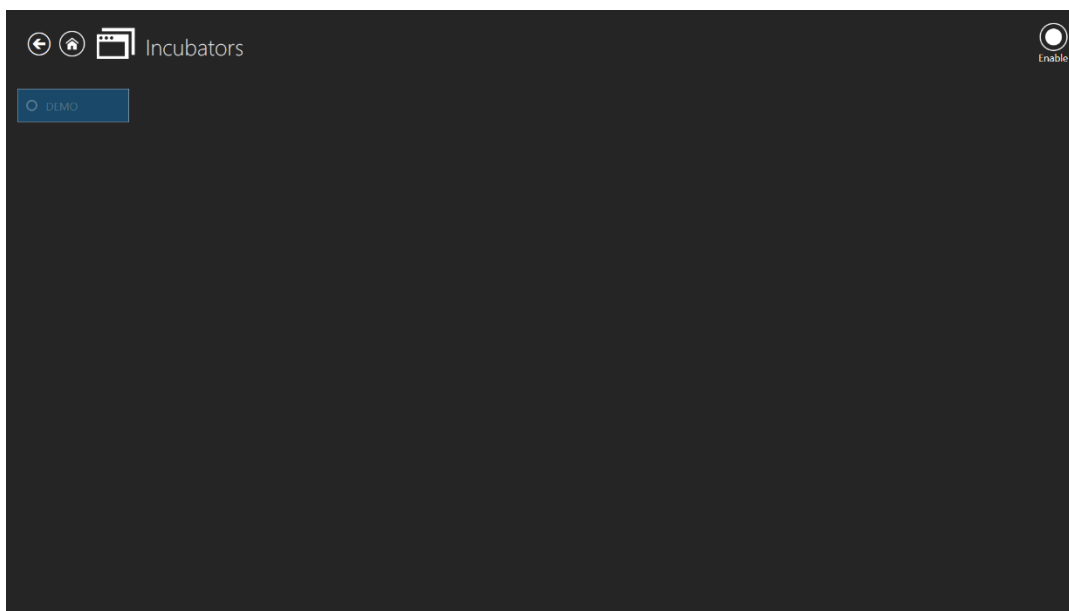


Figure 7.132 “DEMO” incubator is disabled

Double-clicking on the selected incubator will move directly to the incubator’s incubation data log view.

In the picture below, the 1st chamber temperature incubation data is shown.

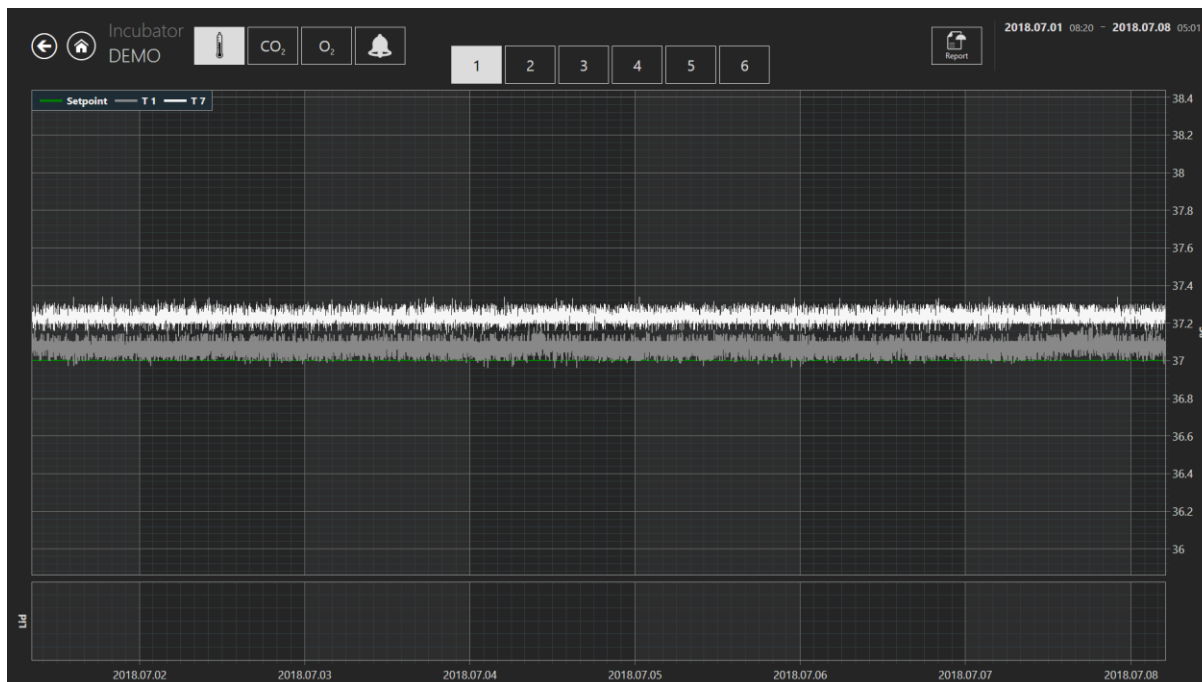


Figure 7.133 “DEMO” incubator temperature incubation data log view

There are few additional options here. In the top right corner of the screen, the user can shift the data to the current month by pressing the “Month” button, current week by pressing the “Week”

button and current day by pressing the “Day” button.

The other option is that by pressing the button that is marked red in the picture below, the user can choose the desired month in the past. The months are listed from the 1st month that MIRI® TL started working.

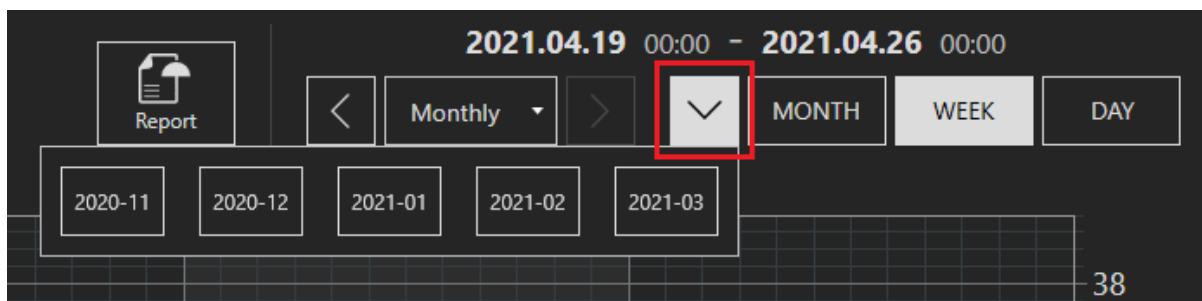


Figure 7.134 Incubation data selection options

The other option is that the user can shift the selected month’s data between “Daily”, “Weekly” and “Monthly” intervals by pressing the appropriate buttons listed below.

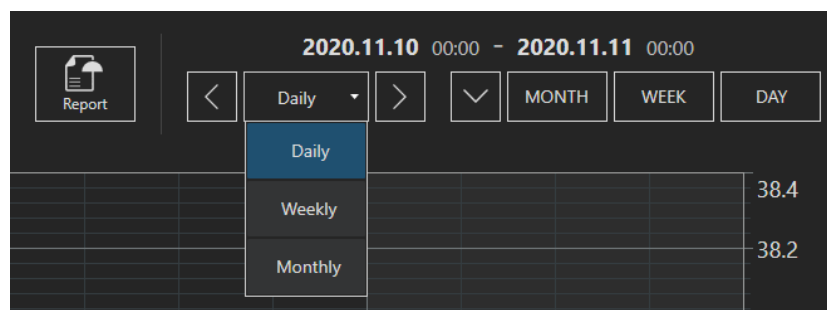


Figure 7.135 Incubation data selection options

After selecting the desired data option, the user can press the button that points to the left (<) or right (>) and, in that way, shift between the data in those intervals.

7.6 Settings

In this section, it is possible to customize the experience when using the MIRI® TL Viewer Software to suit unique user preferences and needs.

Pressing the “Settings” button opens the settings view, which contains the “Annotations”, “Embryo States”, “Shortcuts”, “Score Models”, and “Language” sections.

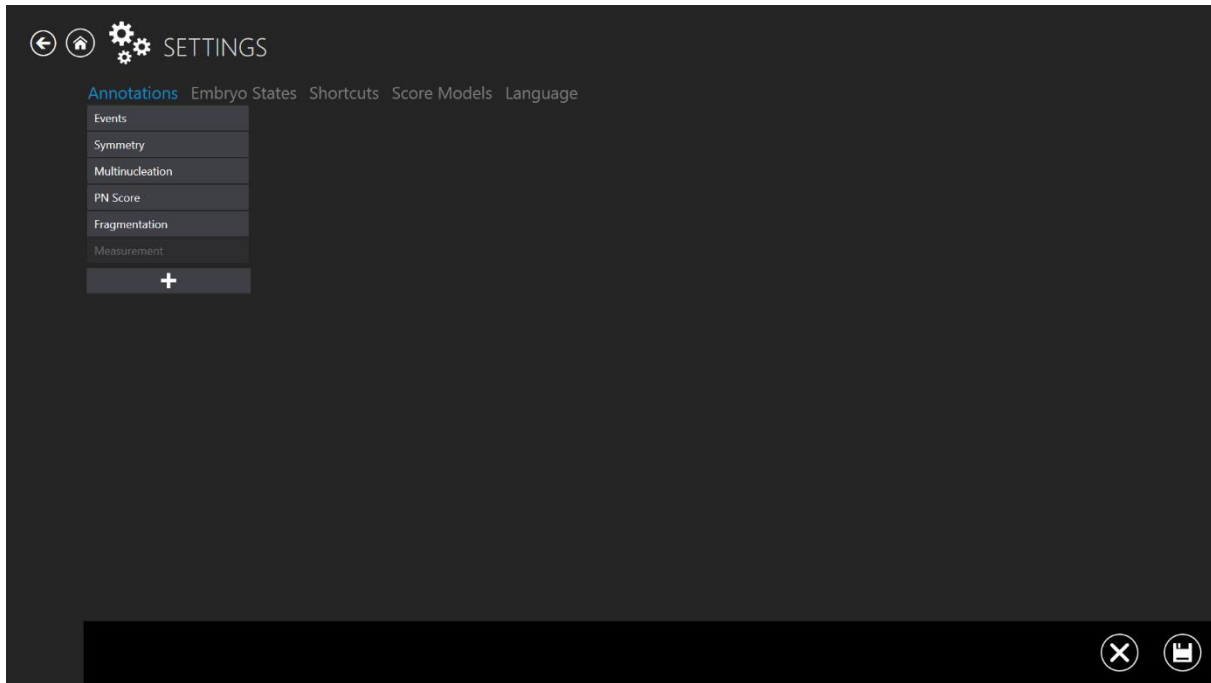


Figure 7.136 Settings view

7.6.1 Annotation modification/creation

It is possible to observe a group of annotations already created in the “Annotations” menu. A new group can be added by pressing the “+” button, which can be found below all annotations.

A created group can be removed from the selection by pressing the delete icon “x” on the lower right side of the display.

Pressing on the “Event” bar will open an event annotation view. Here, the events that comprise the annotations group can be seen. In the picture, t2 (time to the two-cell stage) is shown. It is indicated as “active”, meaning that it will be used in the annotation mode.

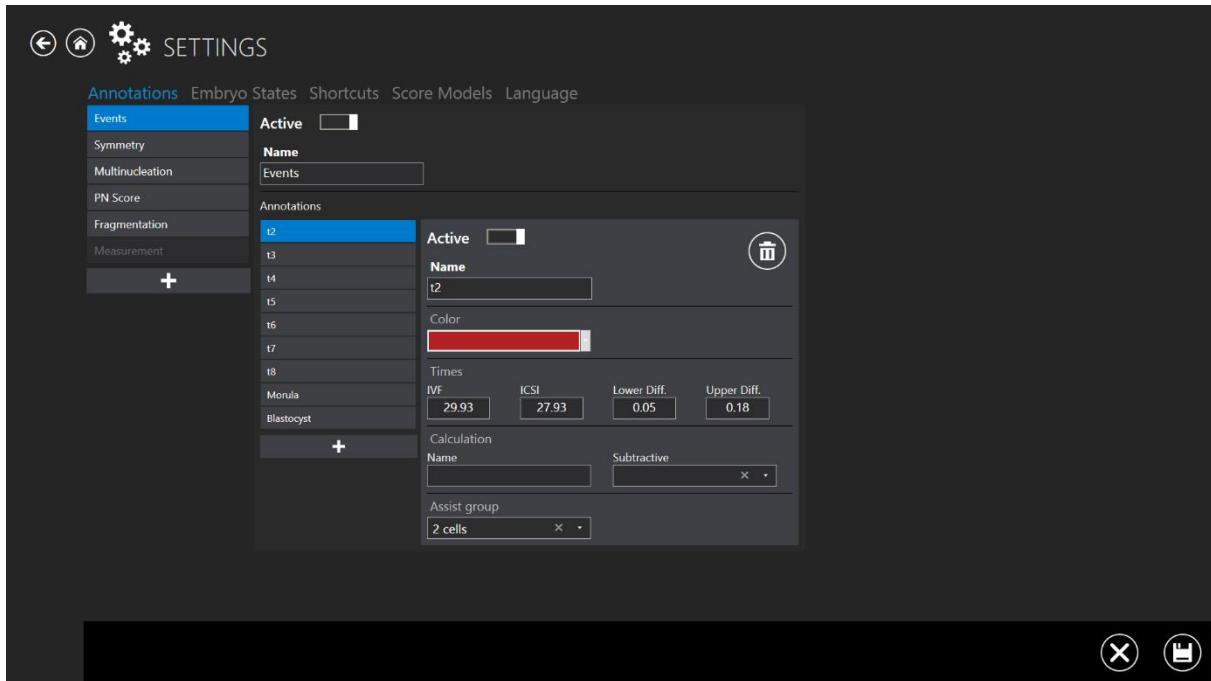


Figure 7.137 Settings – annotations – events view

It has been assigned the color red (the color shown in the context where t2 occurs). Ideal times are set for IVF and ICSI with lower and upper diff.

No calculations are linked to the t2 parameter here.

If the user wants to calculate the time between t2 and t3 automatically, the variables are entered in the calculation field. Then the mathematical function is selected, which will perform the calculation. For example, cc2 is the time difference from 2 cell divisions into 3 cells. The t3 cell division time value will be subtracted from the t2 cell division time value. In that way, the system will automatically calculate cell cycles once the event times have been annotated. Experimentally calculated values can also be set up and tracked.

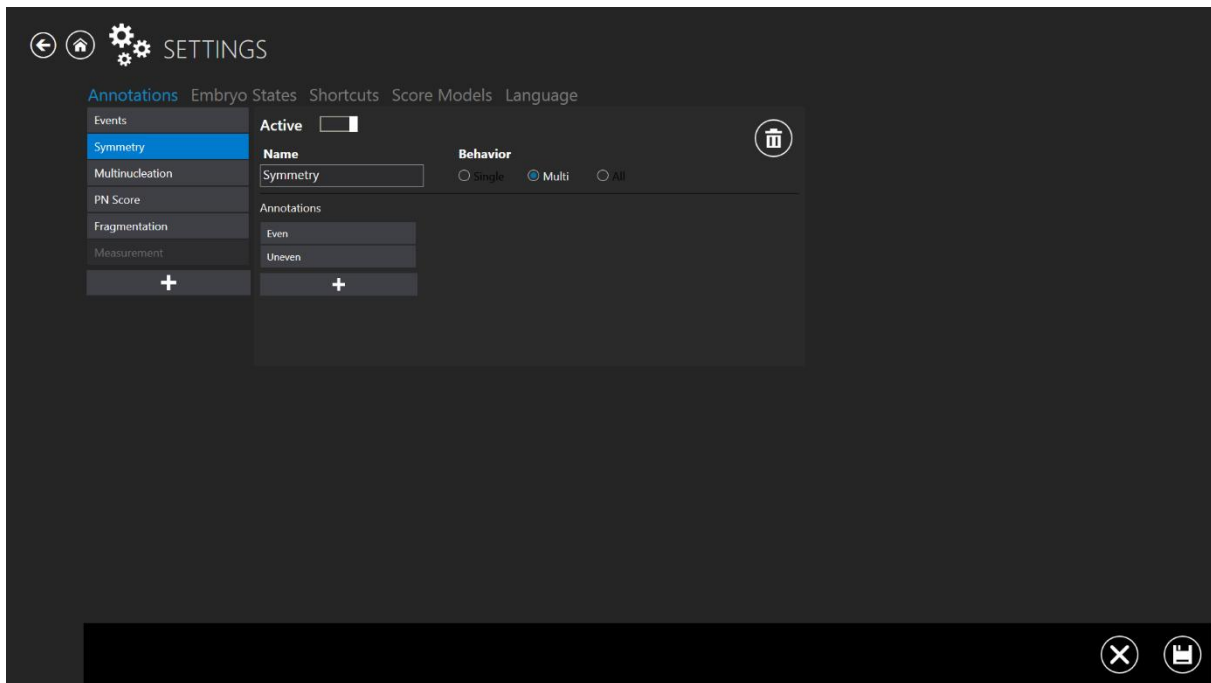


Figure 7.138 Settings – annotations – symmetry view

Events also have behavior that decides how they respond to being annotated. For instance, t2 will only occur once, which means that it is practical to disappear from the event list once assigned a value (annotated). This behavior is called “Single”.

Like symmetry, other things may occur at different stages and should remain selectable after being used once. This behavior is called “Multi”.

The user can also link a group of annotations, and if that is chosen, the rest of the group disappears. This behavior is called “All.”

There are also “Multinucleation,” “PN Score,” “Fragmentation,” and “Measurement” annotations listed.

 If the “Annotations” submenu is left without saving the modifications, a dialog box will appear informing the user about unsaved changes.

7.6.2 Embryo states’ modification/creation

Embryo states submenu allows the user to modify the already-created embryo states or add new ones.

The creation of a new embryo state consists of 4 states:

1. Ability to activate/deactivate the created embryo state.
2. “Key” – one symbol, which will indicate the selected well on a “Dish map”. It must be unique and not overlap with existing ones.
3. “Name” – created embryo state name.
4. Embryo state color selection.

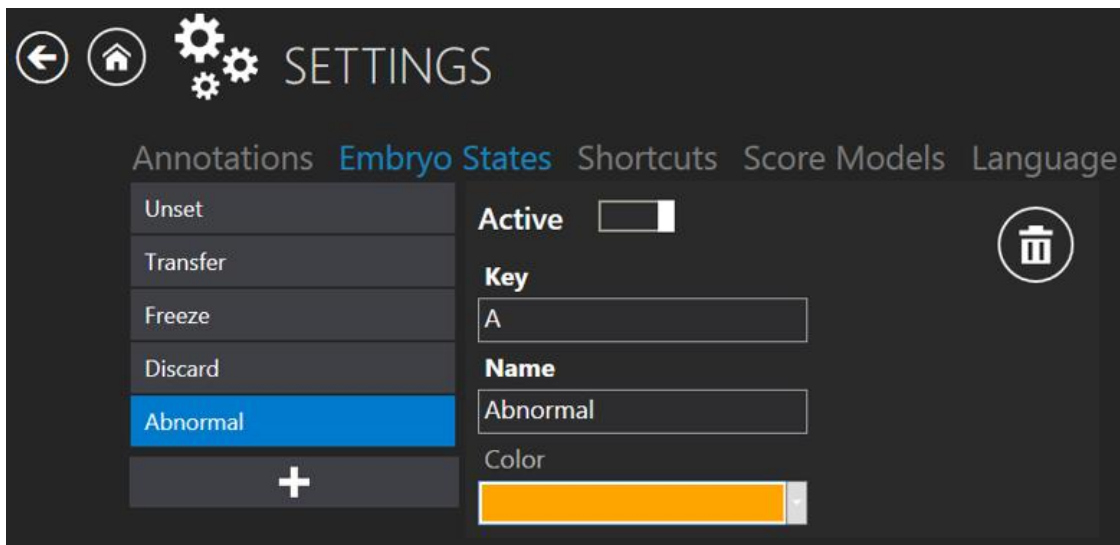


Figure 7.139 Active new embryo state

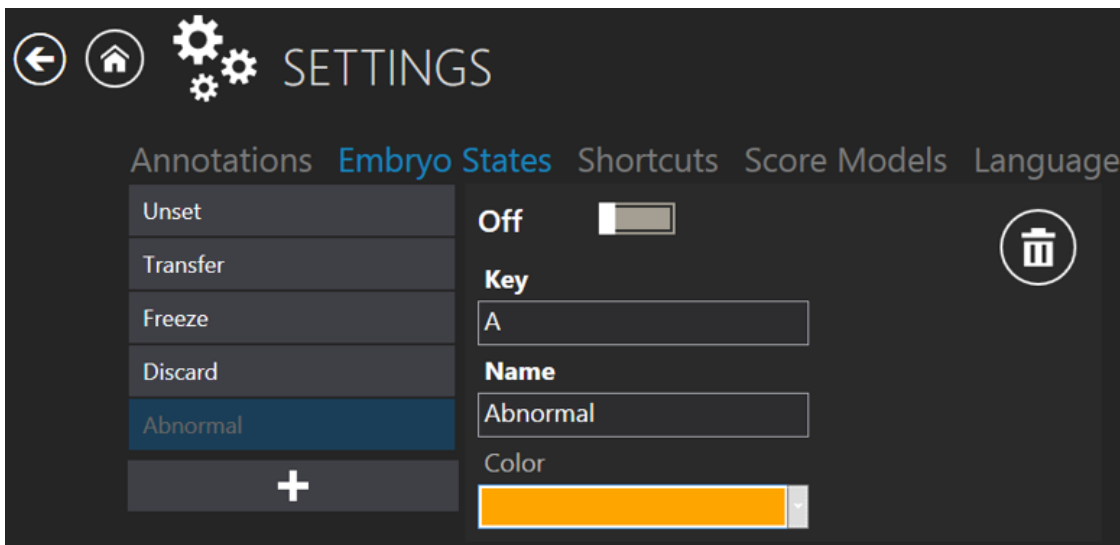


Figure 7.140 Inactive “Abnormal” embryo state

👉 If the “Embryo States” submenu is left without saving the modifications, a dialog box will appear informing the user about unsaved changes.

7.6.3 Shortcuts

The “Shortcuts” submenu allows the user to customize various keyboard shortcuts for a more convenient user experience and a better workflow.

Shortcuts are categorized into different categories where they can be used. Currently, only two categories exist: “Patients” and “Timelapse/Timelapses”. These categories correspond to related menus inside the MIRI® TL Viewer Software, i.e. “Patients” and “Timelapses”.

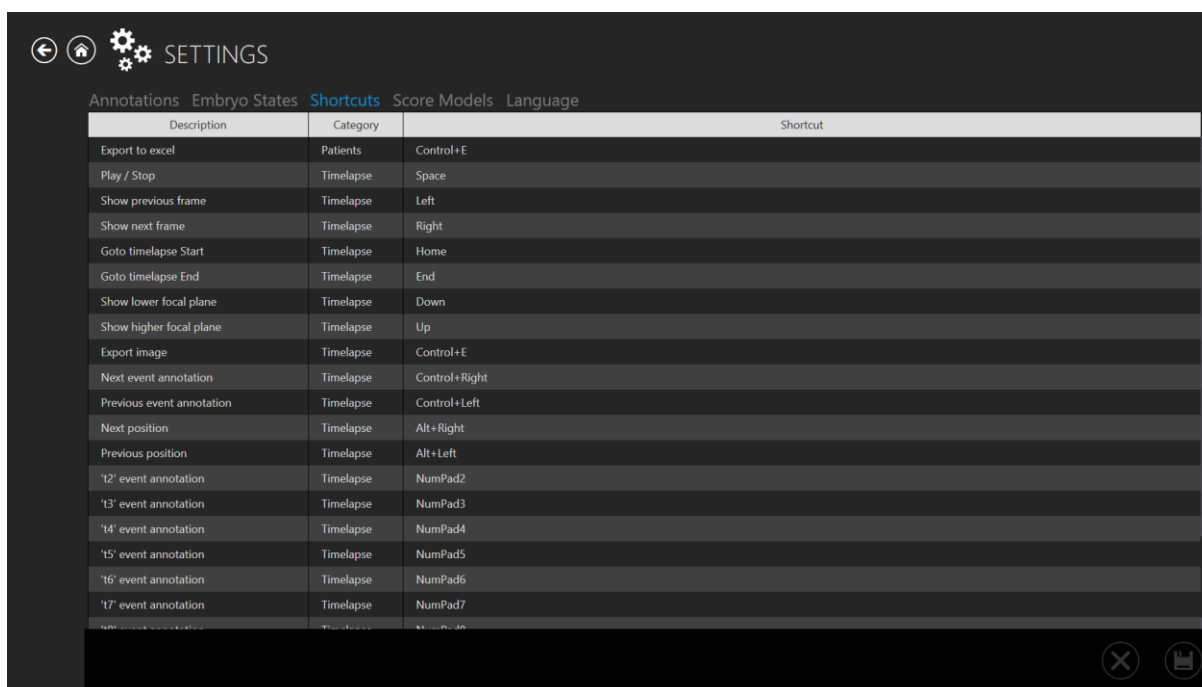


Figure 7.141 Shortcuts submenu

To modify the existing shortcuts, double-click on the shortcut which is to be modified and input the desired combination. It is possible to use the following keys:

- Functional (F1-F12), navigation (“Home”, “End”) & arrow, and NumPad keys can be used.
- Modifier keys, such as “Control”, “Alt”, and “Shift”, can be used to input a key combination, such as “Control+E”, to utilize the alphabetic keys.

After editing the shortcuts, click the “Save” button to save the new shortcut. Also, it is possible to delete the new shortcut and revert to the previous one by pressing the “x” button.

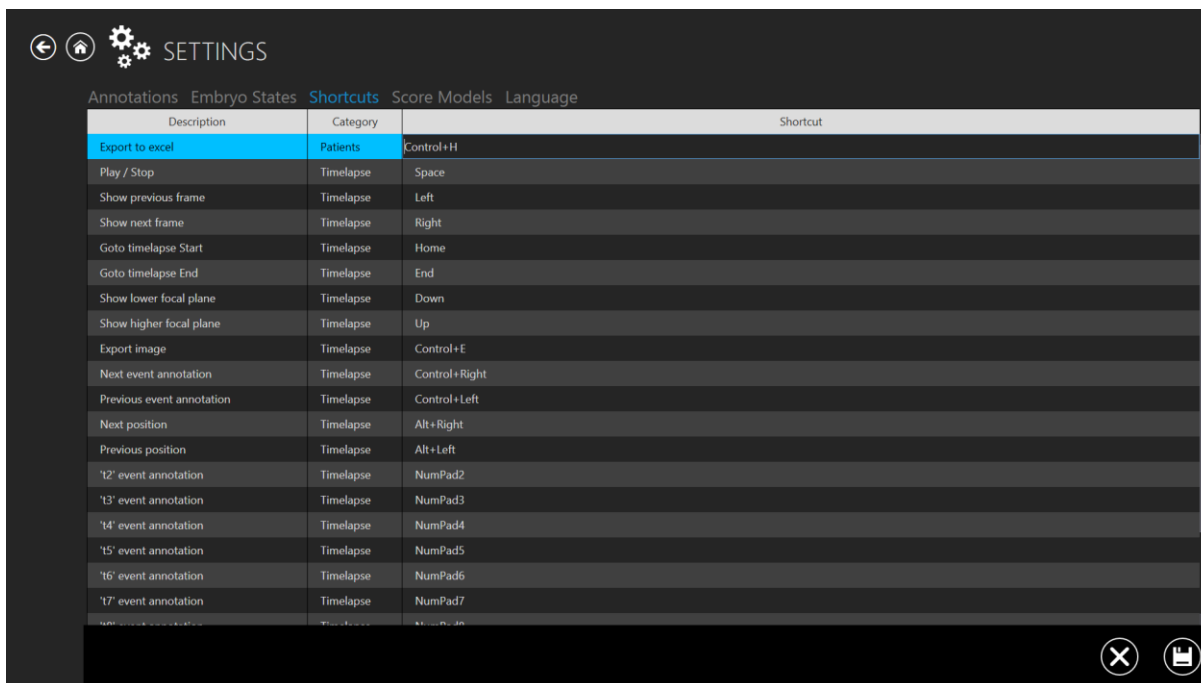


Figure 7.142 Shortcut editing

 Due to Windows limitations, a shortcut containing only the letter of the alphabet (e.g., “A”, “X”, etc.) cannot be used.

 Currently, it is not possible to create additional shortcuts.

Similar shortcuts **cannot** be used inside the same category. For example, the shortcut “Control+Right” cannot be used to move to the next event annotation and the next position at the same time (both of these functions are under the “Timelapse” category). However, the shortcut “Control+Right” **can** be used to export to Excel because the function is in a different (“Patients”) category.

 A “Shortcut 'xxx' is already in use” message will appear if two identical shortcuts are used in the same category.

 The shortcut for annotations does not create a new annotation. Instead, it allows the user to jump directly to the exact time when an existing annotation was created.

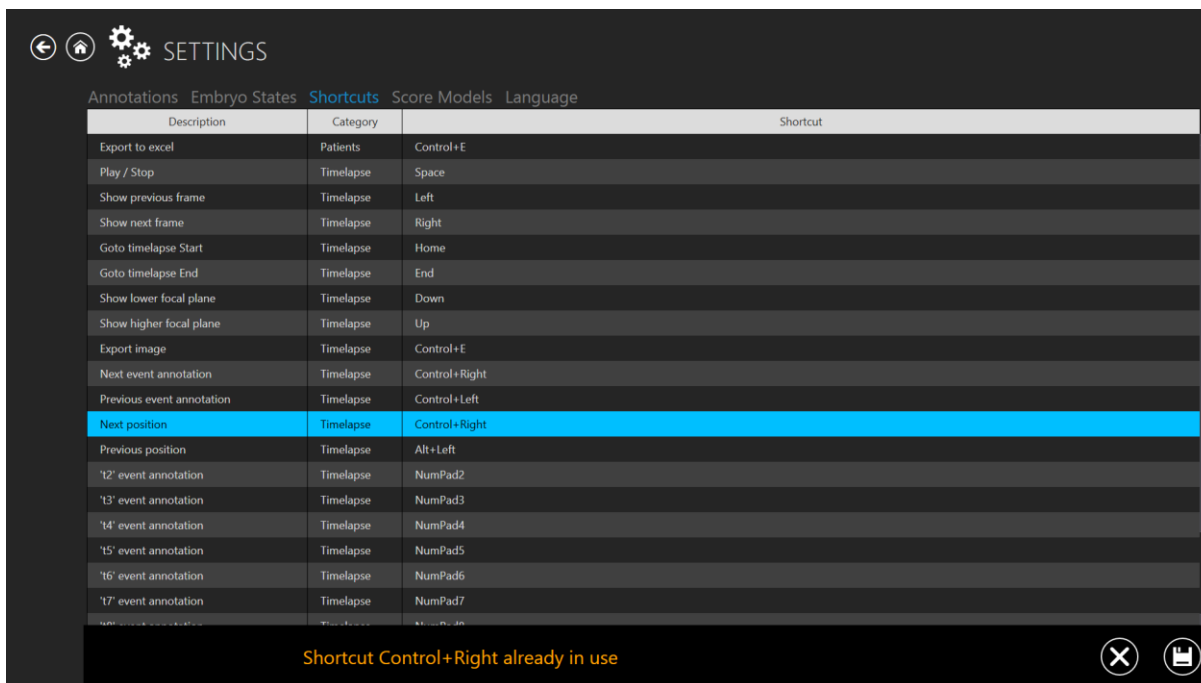


Figure 7.143 Two identical shortcuts in-use scenario

👉 If the “Shortcuts” submenu is left without saving the modifications, a dialog box will appear informing the user about unsaved changes.

7.6.4 Score model creation

There is a function in the “Settings” menu, called “Score Models”.

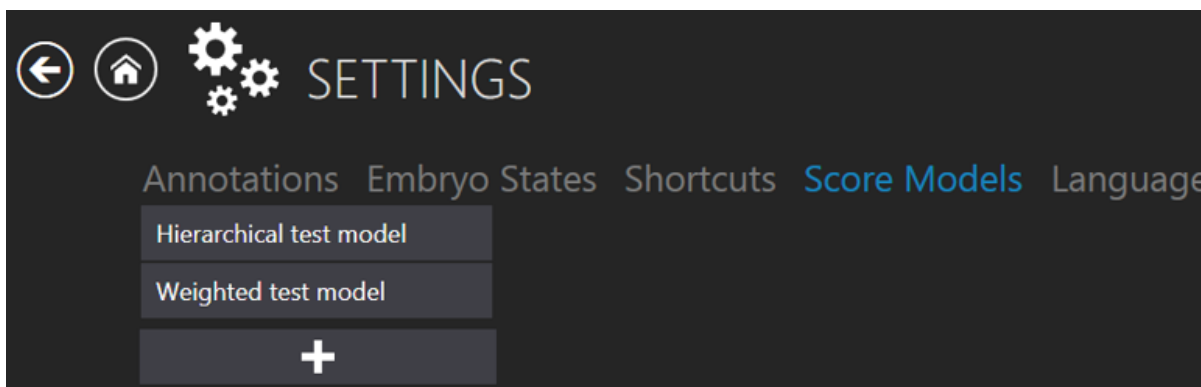


Figure 7.144 Score models

Pressing the “+” button displays a score model input where the user can create a desired embryo score model.

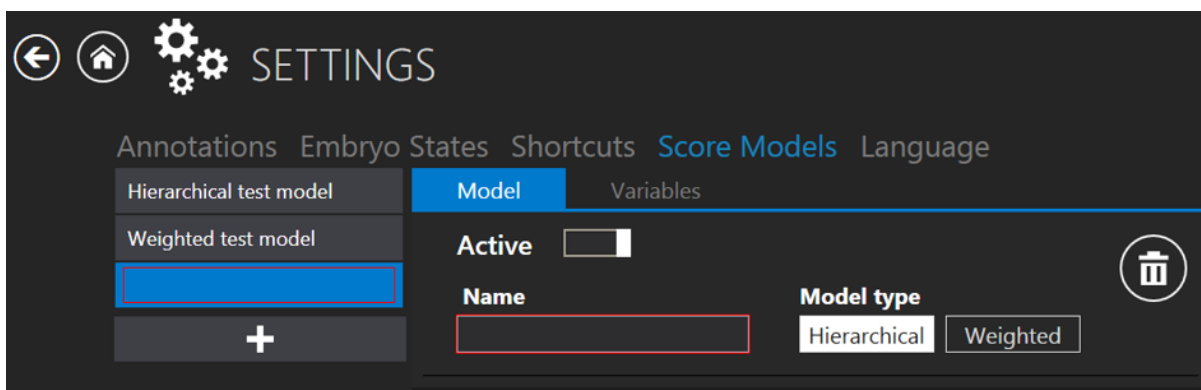


Figure 7.145 A new embryo score model creation window

Choosing the model type

The user can choose between two model types: “Hierarchical” and “Weighted.” The main difference between these model types is that “Hierarchical” is plotted graphically, whereas “Weighted” is calculated using a formula.

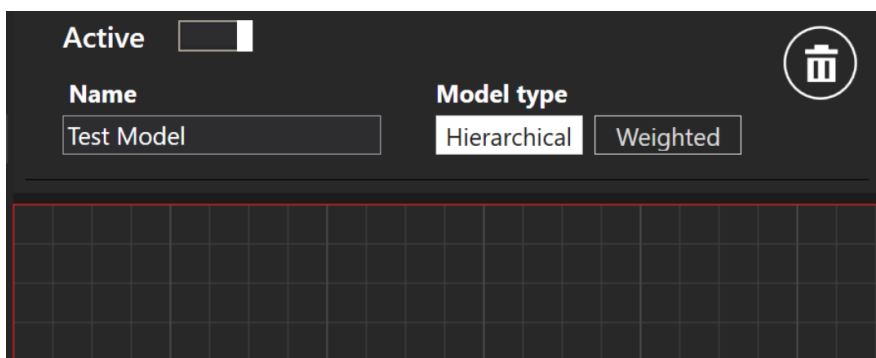


Figure 7.146 “Hierarchical” model type

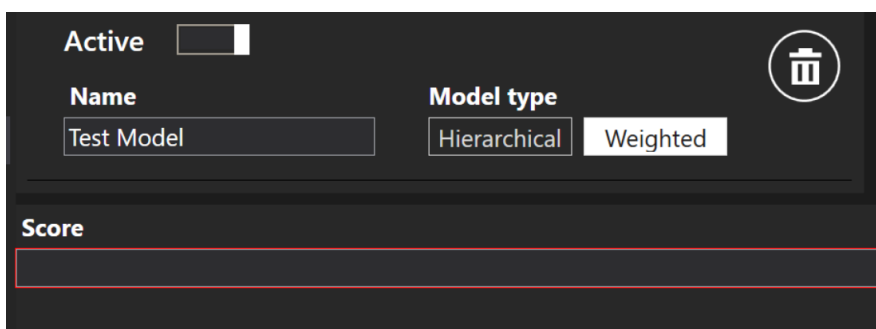


Figure 7.147 “Weighted” model type

The model can be activated or inactivated by pressing the button (marked red) in the picture below.

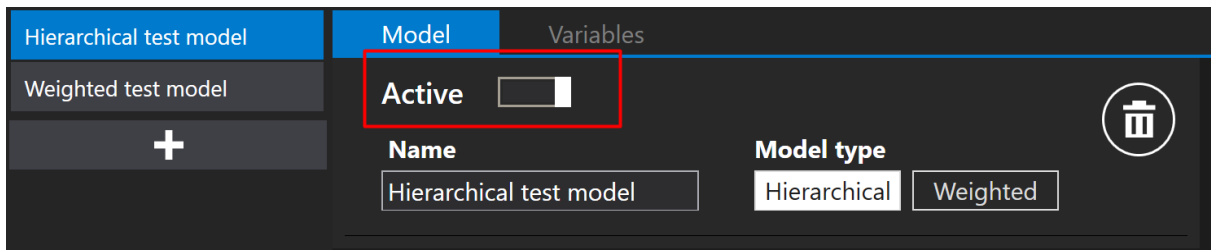


Figure 7.148 Activating or inactivating the selected score model

Variable creation

Near the “Model” button, there is also a “Variables” button. Pressing it displays a variable list containing predefined variables automatically taken from the events calculation annotation list.

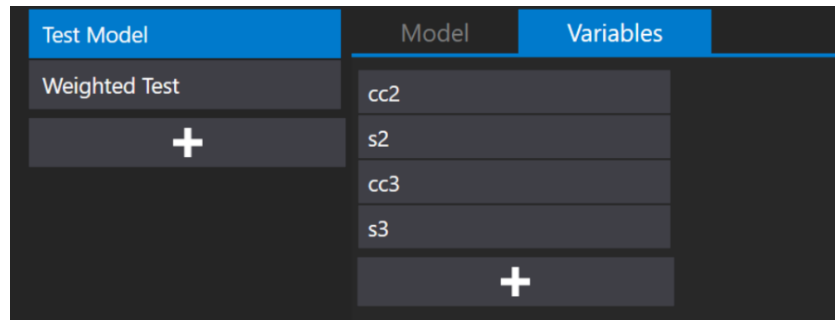


Figure 7.149 Listed “Variables” from the annotation list

By pressing the “+” button, the user can create a new variable by entering the name and formula.

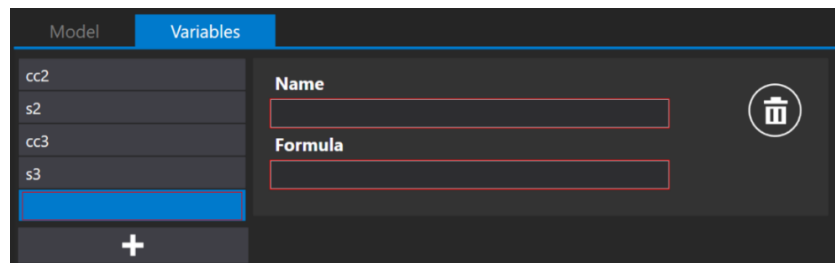


Figure 7.150 New variable creation

 The variable name cannot consist of symbols, such as – “+”, “-”, “/”, etc. If the symbol is used, the box will be circled in red.

By pressing the “e” letter in the “Formula” box, a list of “Events” annotations will appear, and the user can choose the desired event instead of writing it all down.

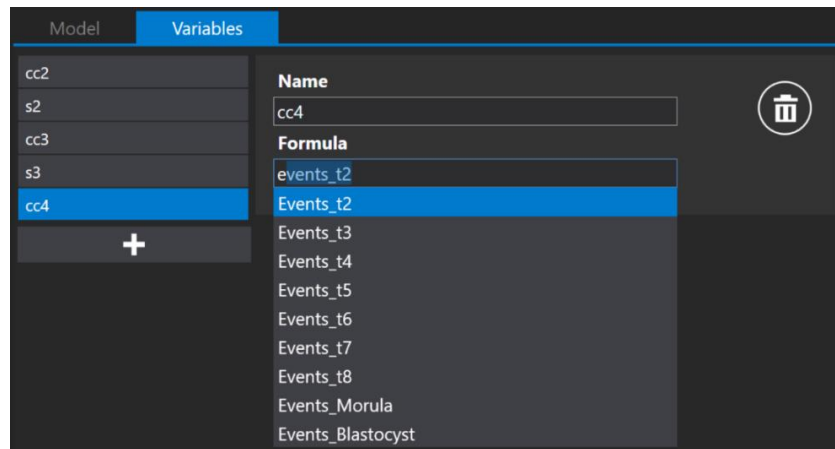


Figure 7.151 New variable creation

👉 When the “Formula” field has some text to invoke the display of the events list, the “Space” key should be used. Otherwise, the user will need to write the annotation group name, underscore and annotation name (e.g., events_t2).

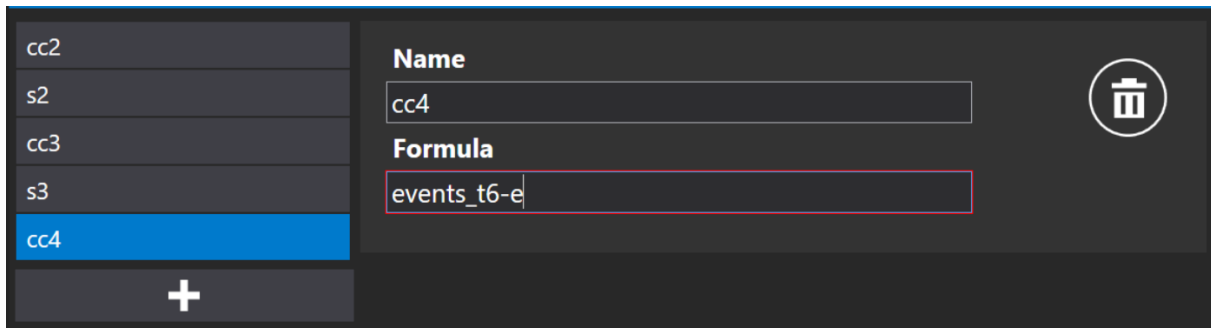


Figure 7.152 Formula creation without pressing the “Space” key

👉 The red square around “Formula” will disappear if the variable formula is written correctly.

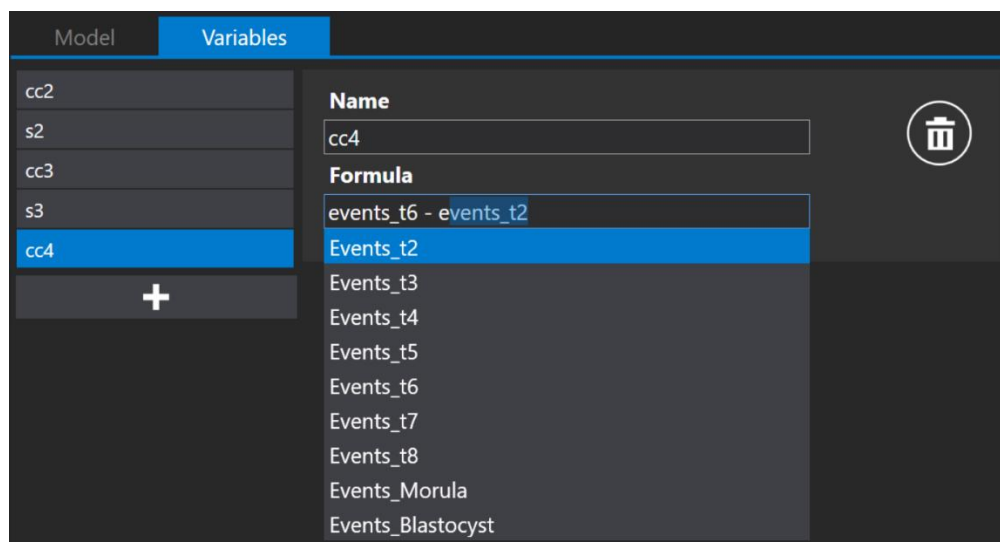


Figure 7.153 Formula creation when pressing the “Space” key

 If users create additional variables, they will only apply for a specific embryo score model. When creating a new embryo score model, variables should also be created separately.

Press the save button located at the bottom of the screen. If everything is filled correctly, the “Saved” message will appear; if not, the “Score model variables has errors” message will appear.

7.6.4.1 Hierarchical score models

The first thing the user should do is enter a name for the hierarchical embryo score model. After entering the name, the red square around “Name” will disappear.

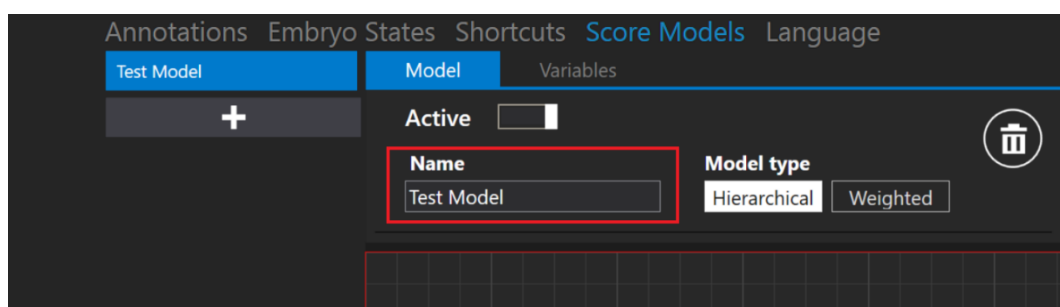


Figure 7.154 Naming the hierarchical embryo score model

7.6.4.1.1 Conditional node creation

Below the name field, there is an area where the user can place nodes. By pressing the right mouse key on the area, a list of possible actions will be displayed. The user can add a conditional node or result node or remove the selected node (only applicable when a node is selected).

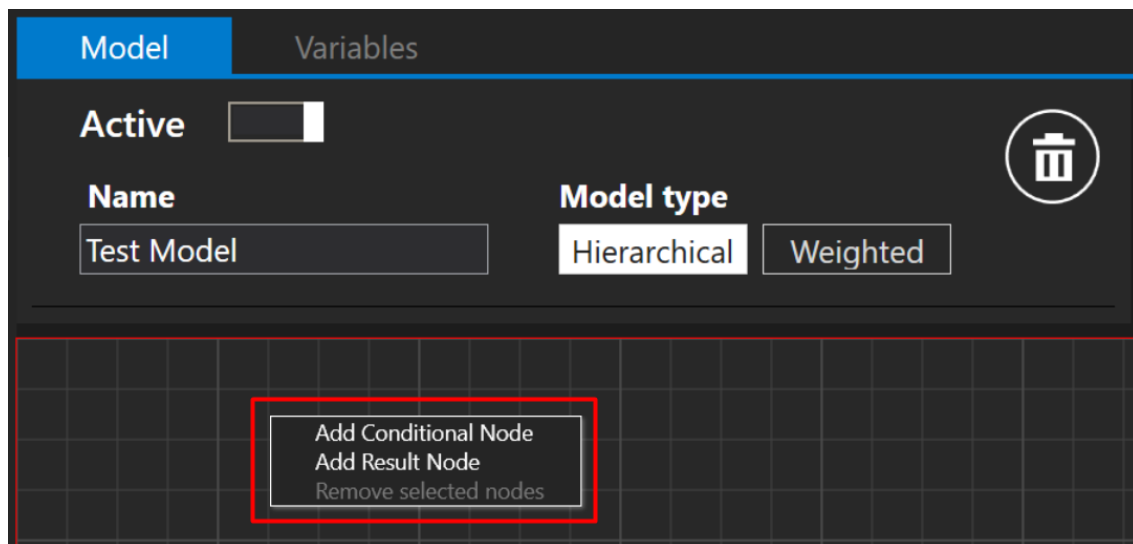


Figure 7.155 New conditional or result node creation

A “Condition” input will appear when the “Add Conditional Node” is pressed.

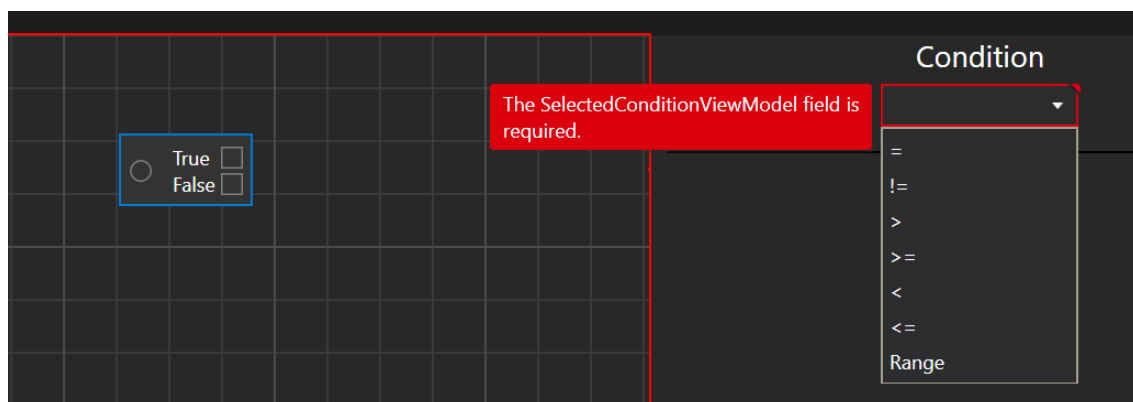


Figure 7.156 Available conditions

The user can choose between seven conditions: **equal** (symbol “=”), **not equal** (symbol “!=”), **more than** (symbol “>”), **more than or equal** (symbol “>=”), **less than** (symbol “<”), **less than or equal** (symbol “<=”) and **Range**.

When the desired condition is chosen, it will automatically display a list with “Variables” and annotations.

 The system will automatically choose the first variable from the list!

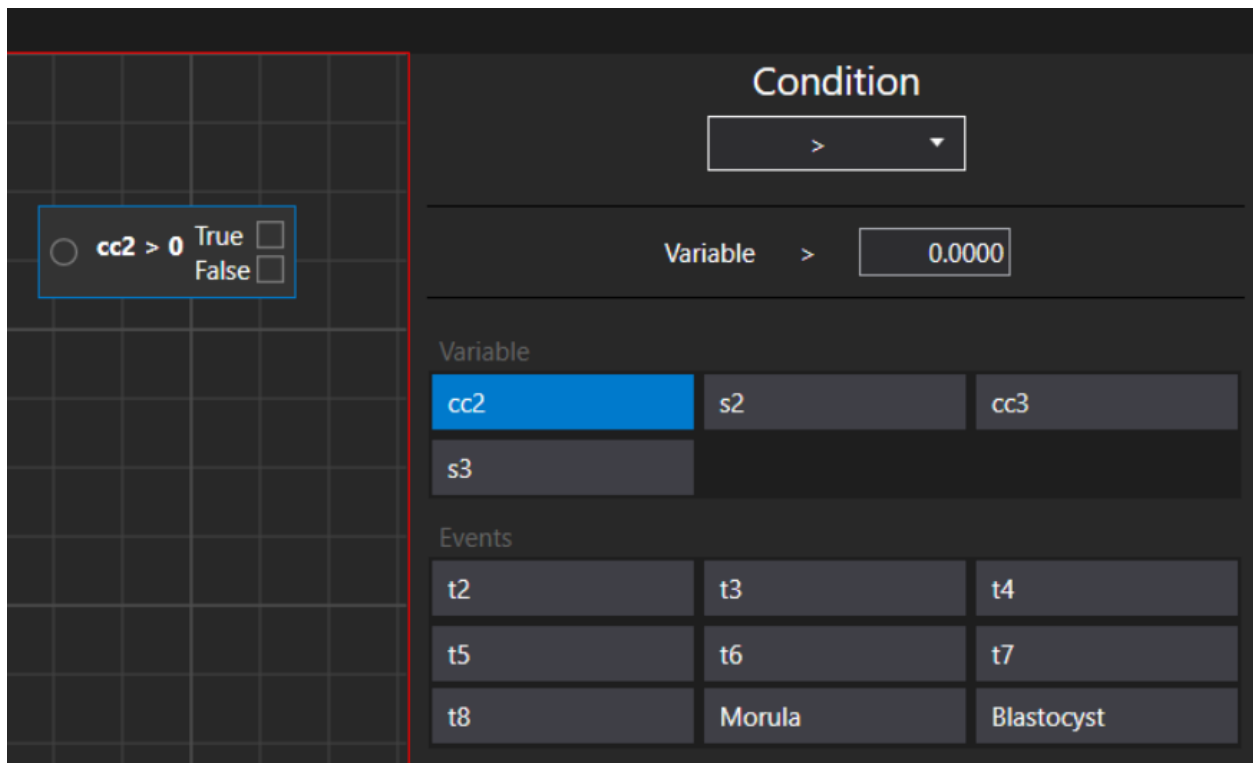


Figure 7.157 “More than” condition and annotation options

 Only annotations with the group behavior option “Single” or “All” will be displayed in this menu. For more information related to the group behavior refer to the 7.6.1 “Annotation modification/creation” section of the User Manual.

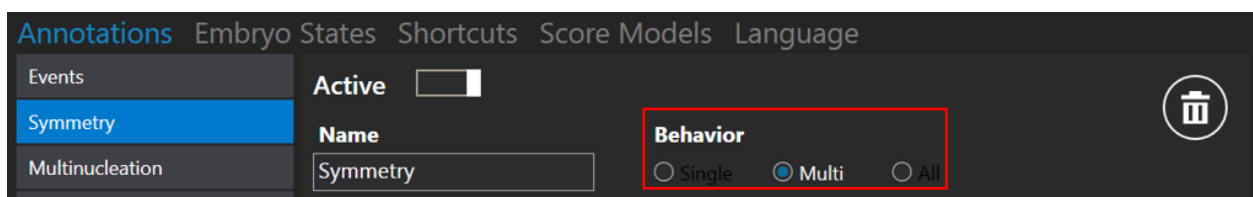


Figure 7.158 Possible annotations “Behavior” options

 A hierarchical score model cannot have two separate conditional nodes in one score model. It can have multiple conditional nodes, but they must be linked to one another.

7.6.4.1.2 Result node creation

Let's set that the "cc2" variable is more than 10. ("cc2" variable means the amount of time that is passed between the "t2" event and the "t3" event).

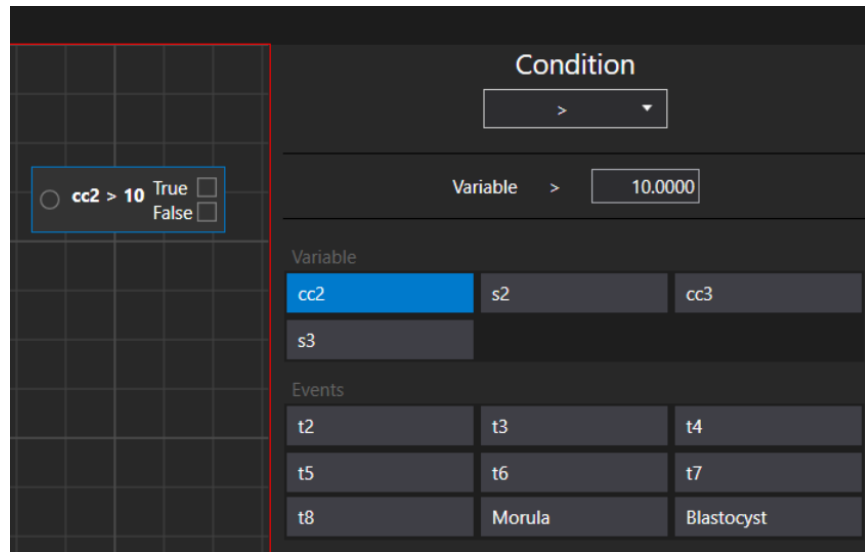


Figure 7.159 "cc2" variable is set to be more than 10

When the conditional node is created, the next step is to create a result node, which the user can do by pressing the right mouse key on the area of a node and choosing the "Add Result Node" action.

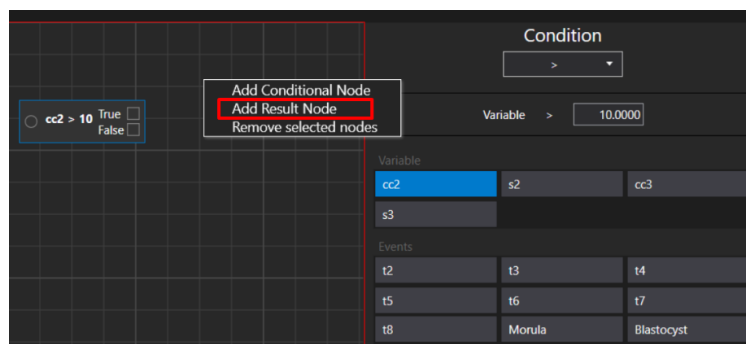


Figure 7.160 "Add Result Node" window

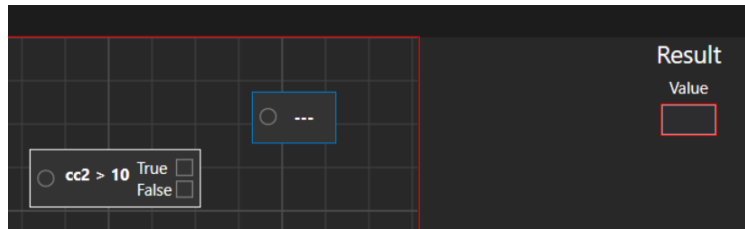


Figure 7.161 Created result node without set “value”

The value of the result node can be created according to any user's preferences. In this case, we will set it “Acceptable”. It will be set as a “True” value. For the “False” value, let’s create a “Not acceptable” result node.

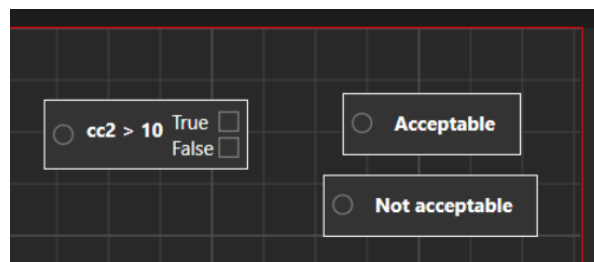


Figure 7.162 Conditional node with 2 result nodes

After the result nodes are created, the conditional node needs to be linked with each result node. It can be linked by pressing the left mouse key on the conditional node’s quadrilateral and then moving the appeared line towards the circle located in the result node.



Figure 7.163 Conditional node with connected “Acceptable” result node

 In the ACTIVE score model, the "Conditional Node" and "Result Nodes" must be linked in order to save the score model. If an attempt to save it without linking these nodes is made, a "Score model has errors" message will be received. To save the score model while editing, deactivate it.

 The embryo score model will be saved only when created according to the steps described above, and the saved button on the right side is pressed. The user will be notified by the “Saved” message.

7.6.4.1.3 Removing the conditional and result nodes

The link between the conditional and result nodes can be deleted by hovering the mouse on the created line. When it turns into small blue lines, click on it using the left mouse key.

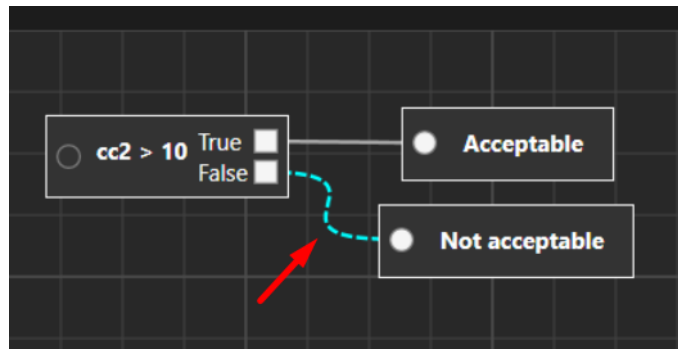


Figure 7.164 Removing the link between conditional and result nodes

The conditional or result node can be deleted by pressing the right mouse key over the selected node. A possible "Remove node" action will be displayed.

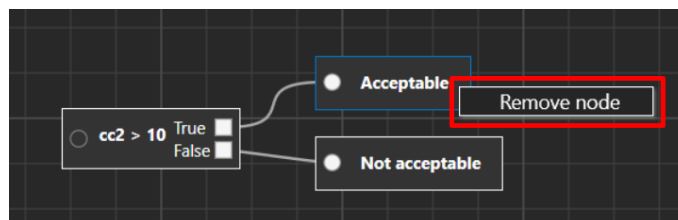


Figure 7.165 Removing "Acceptable" result node

The user can delete undesired nodes using two different methods. The first method involves moving the mouse to and marking all nodes.

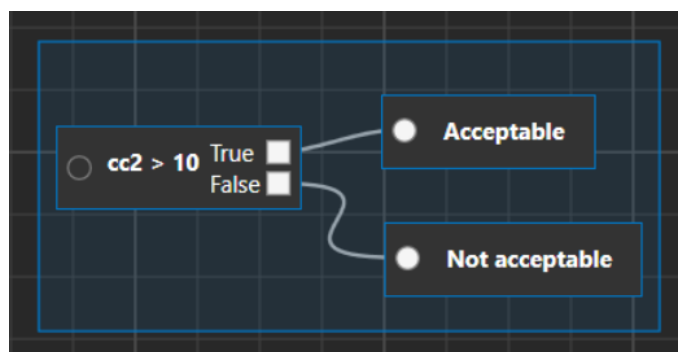


Figure 7.166 Selecting all the nodes

After the nodes are selected (it will be marked with a blue line around them), press the right mouse key on the cell box window and choose “Remove selected nodes” option.

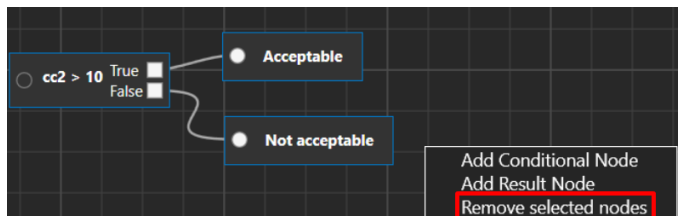


Figure 7.167 Removing all selected nodes

The second method is to click on the desired nodes one by one while holding the “Ctrl” key. After all the nodes are selected, please repeat the removing step above.

7.6.4.1.4 Additional functions

When pressing and holding the right mouse key on the cell box, the user can move the embryo score view.

The user can maximize or minimize the view by using the mouse scroll wheel.

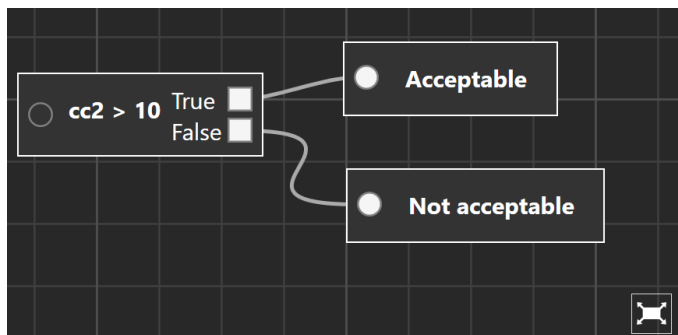


Figure 7.168 Maximized embryo score model view

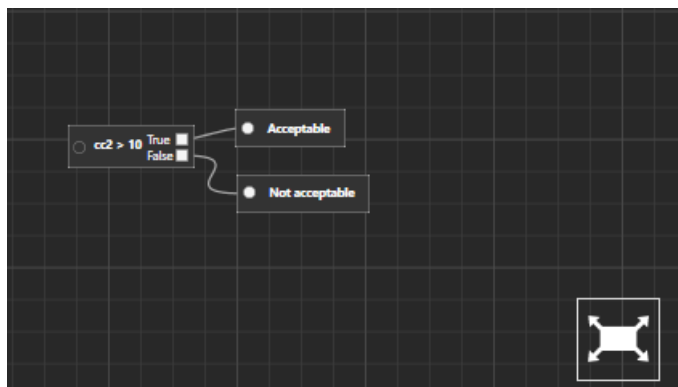


Figure 7.169 Minimized embryo score model view

By pressing the “Reset” button, the view will go back to its initial creation stage.

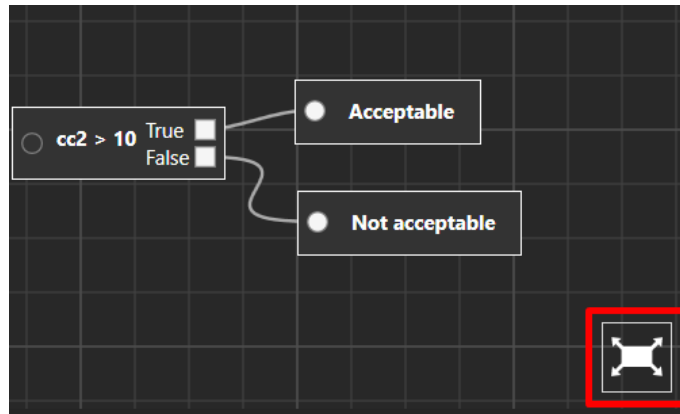


Figure 7.170 Resetting the initial score model view

The nodes can be moved in all cell box window by selecting them and simply moving using the mouse key. Multiple nodes (selected while holding the “Ctrl” key) will move simultaneously. The node's link line will be adjusted automatically.



Figure 7.171 Moving the result nodes simultaneously

7.6.4.2 Weighted score models

The first thing the user should do is enter a name for the weighted embryo score model. After the name is entered, the red square around “Name” will disappear.

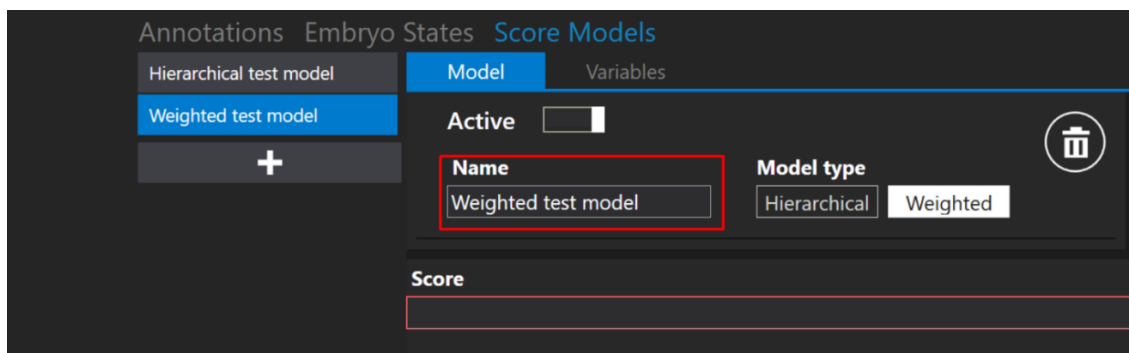
The screenshot shows the 'Score Models' tab in a software interface. On the left, there are three buttons: 'Hierarchical test model', 'Weighted test model' (which is highlighted in blue), and a '+' button. The main area has a 'Model' sub-tab. It contains an 'Active' toggle switch, a 'Name' text input field with 'Weighted test model' entered (this field is surrounded by a red square), and a 'Model type' section with 'Hierarchical' and 'Weighted' buttons. Below these is a 'Score' section with an empty text input field. A trash icon is visible in the top right corner.

Figure 7.172 Naming the weighted embryo score model

By pressing the “e” letter in the “Score” box, there will be a list where the user can choose the desired event instead of writing it all down.

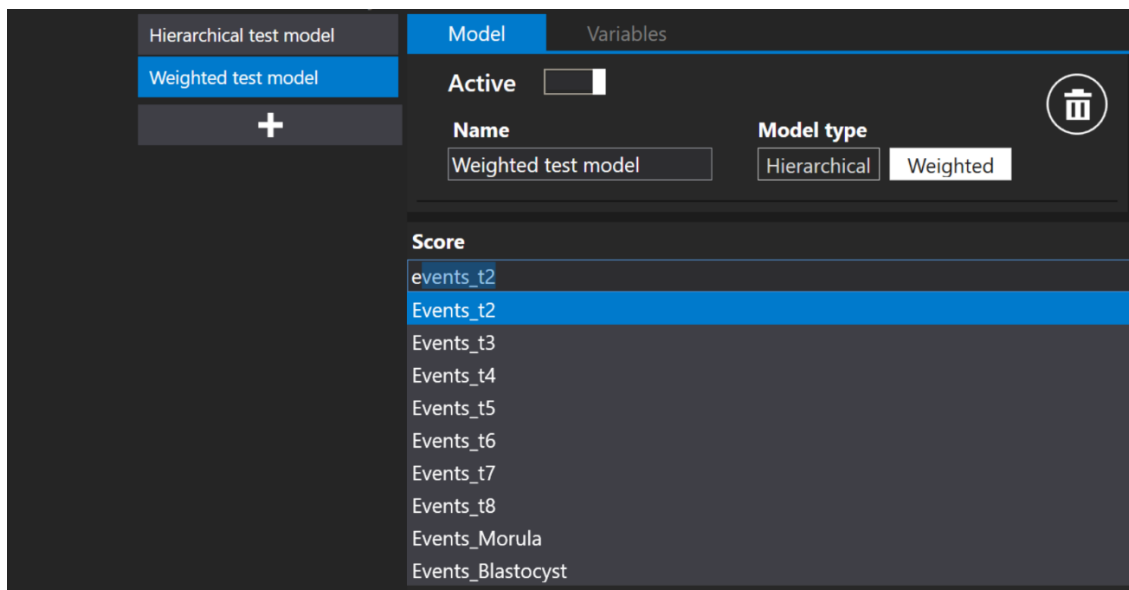
This screenshot shows the same interface as Figure 7.172, but with the 'Score' dropdown menu open. The dropdown list contains the following items: 'events_t2', 'Events_t2' (highlighted in blue), 'Events_t3', 'Events_t4', 'Events_t5', 'Events_t6', 'Events_t7', 'Events_t8', 'Events_Morula', and 'Events_Blastocyst'. The rest of the interface remains the same.

Figure 7.173 New score creation

 The same rules apply to creating a “Score” formula as when creating the “Variables” formula. For more information, please read the “Variables creation” section.

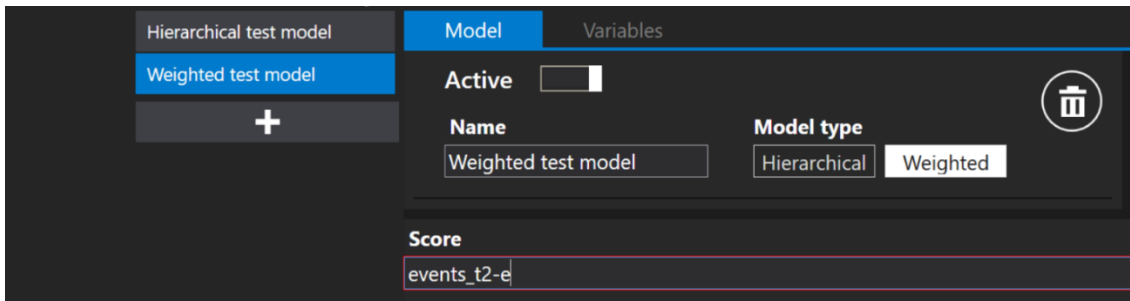


Figure 7.174 New score creation without using the “Space” key

 The red square around “Score” will disappear if the score formula is written correctly.

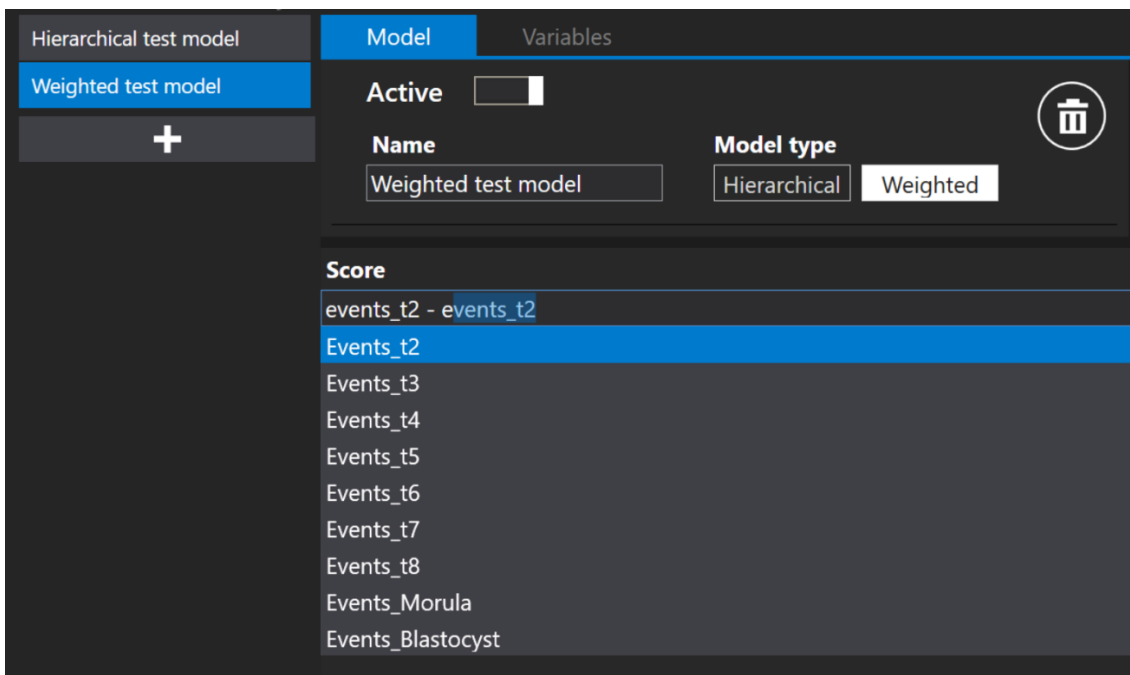


Figure 7.175 New score creation using the “Space” key

7.6.4.3 Deleting the score models

The created embryo score model can be deleted by pressing the “Trash bin” button near the “Model type”.

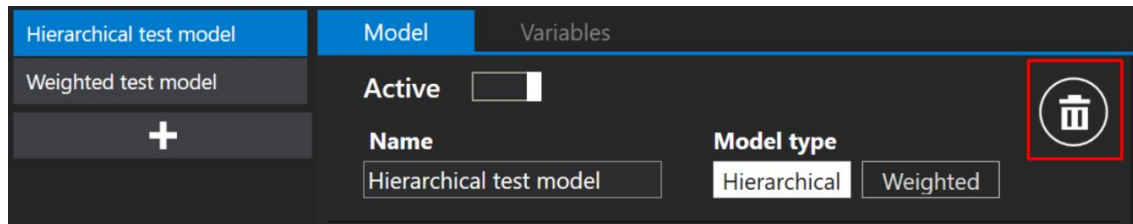


Figure 7.176 “Trash bin” button to delete created embryo score model

The embryo score model cannot be deleted if assigned to a specific timelapse. At the bottom of the view, a “Score model cannot be deleted” message will appear.

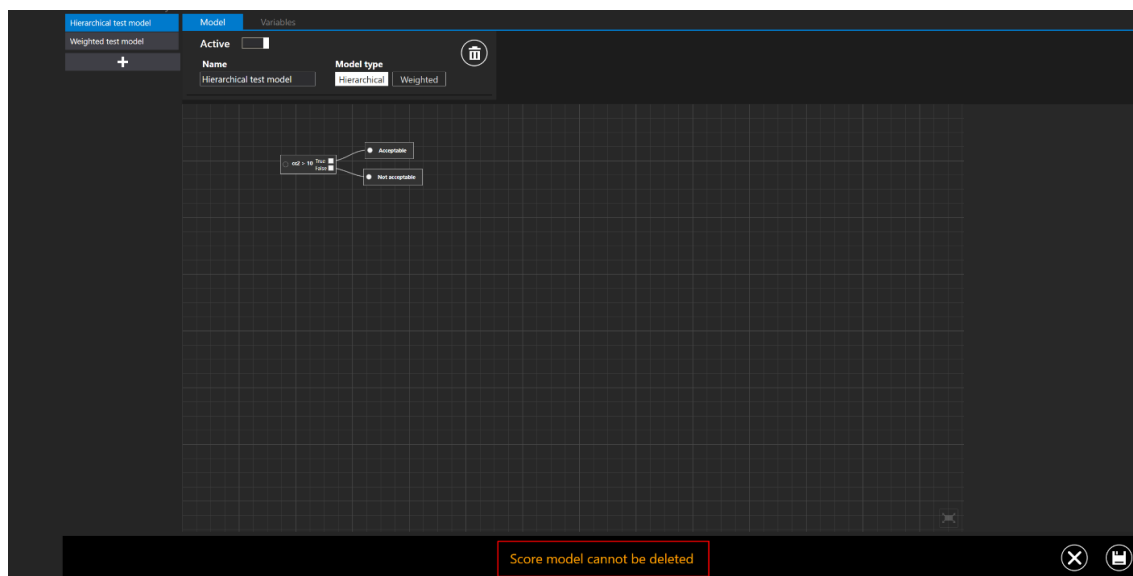


Figure 7.177 Error message when trying to delete embryo score model which is assigned to a timelapse

👉 The “x” button located at the bottom of the screen will get back to the main “Score Models” view.

👉 If the “Score models” submenu is left without saving the modifications, a dialog box will appear informing the user about unsaved changes.

7.6.5 Language

The “Languages” submenu allows the user to choose between various display languages, supported in the MIRI® TL Viewer Software.

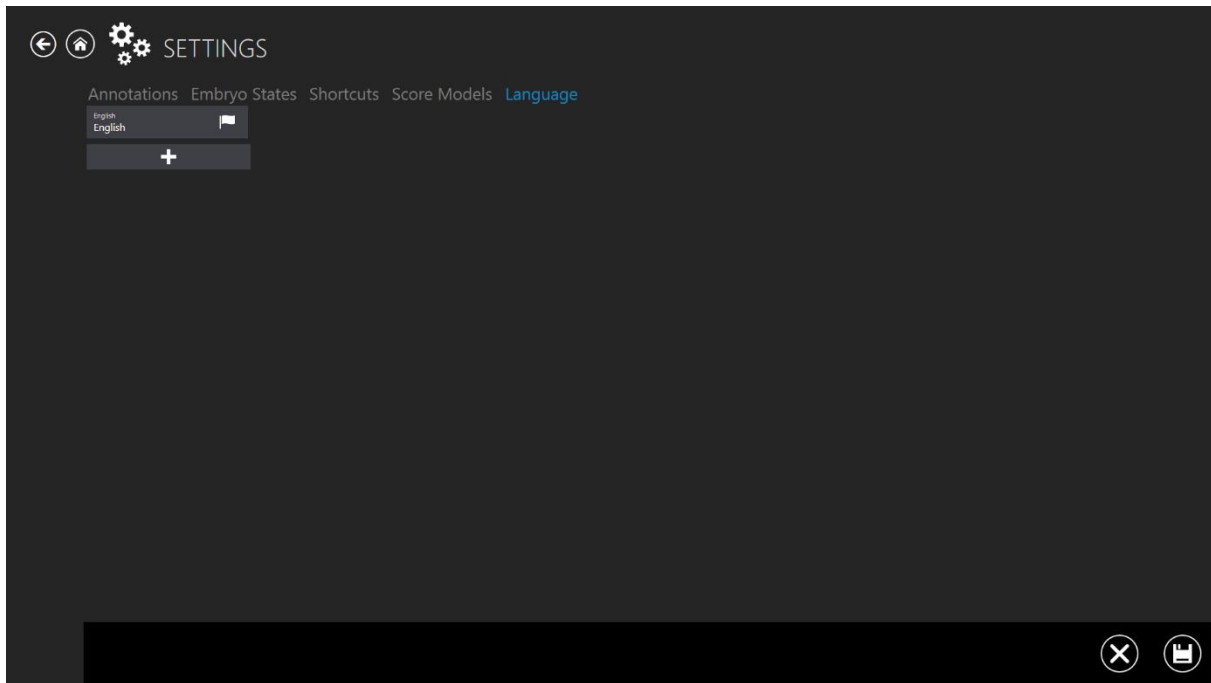


Figure 7.178 Language submenu

 A “Flag” represents the currently enabled language option.

To add an additional language option, press the “+” button. A menu with available languages will be displayed. Choose the desired language option and click the “✓” button to save the language choice.

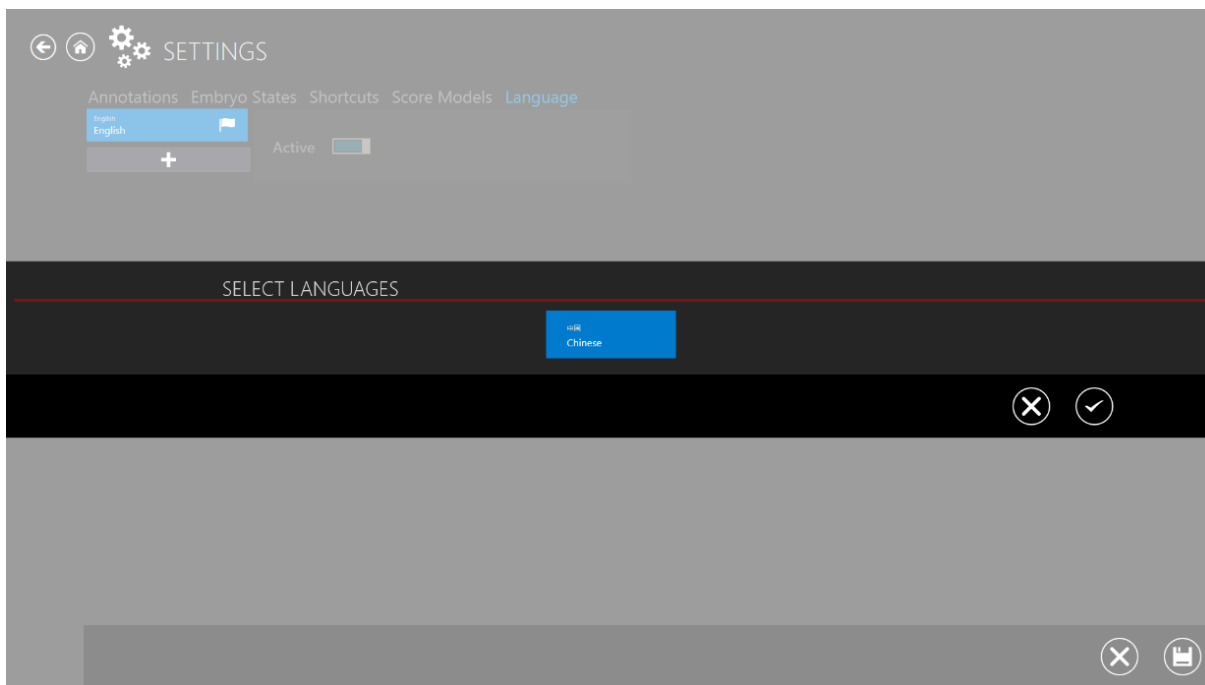


Figure 7.179 Language options

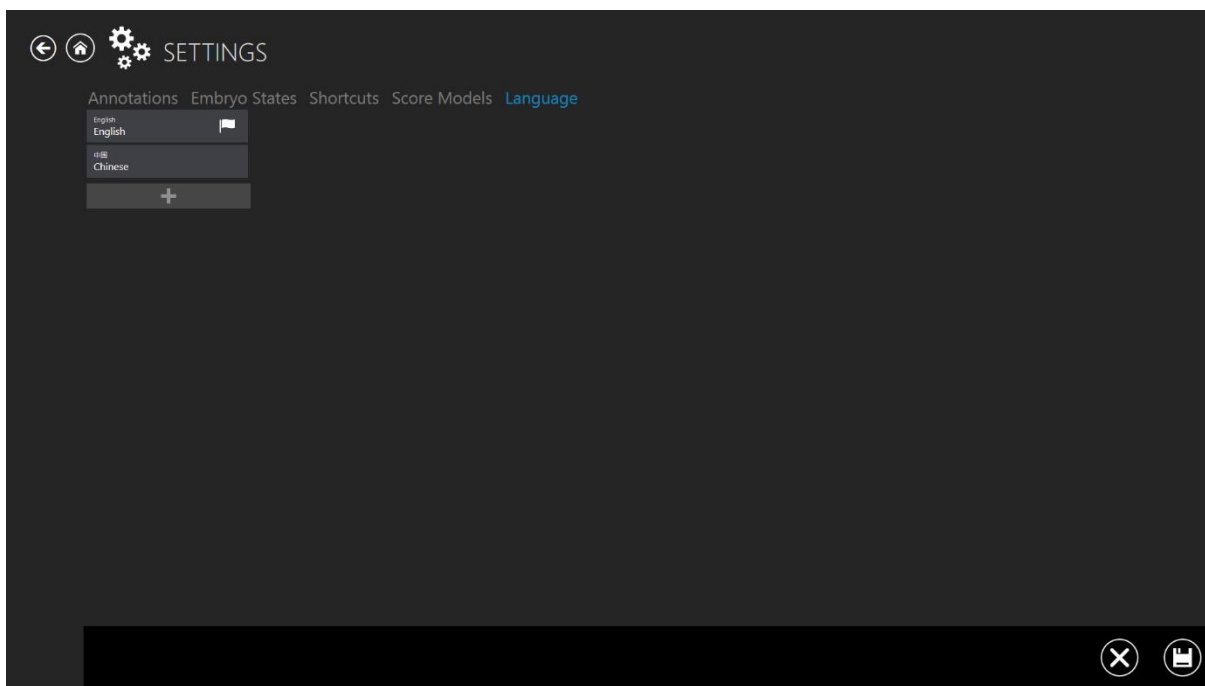


Figure 7.180 Additional language chosen

 Only the Chinese language option is available in the 1.22.2.0 software version release.

To activate the added language, click on the desired option and press the box near “Inactive”. The new language has been enabled. To switch the display language, click on the “Save” button in the lower right corner.

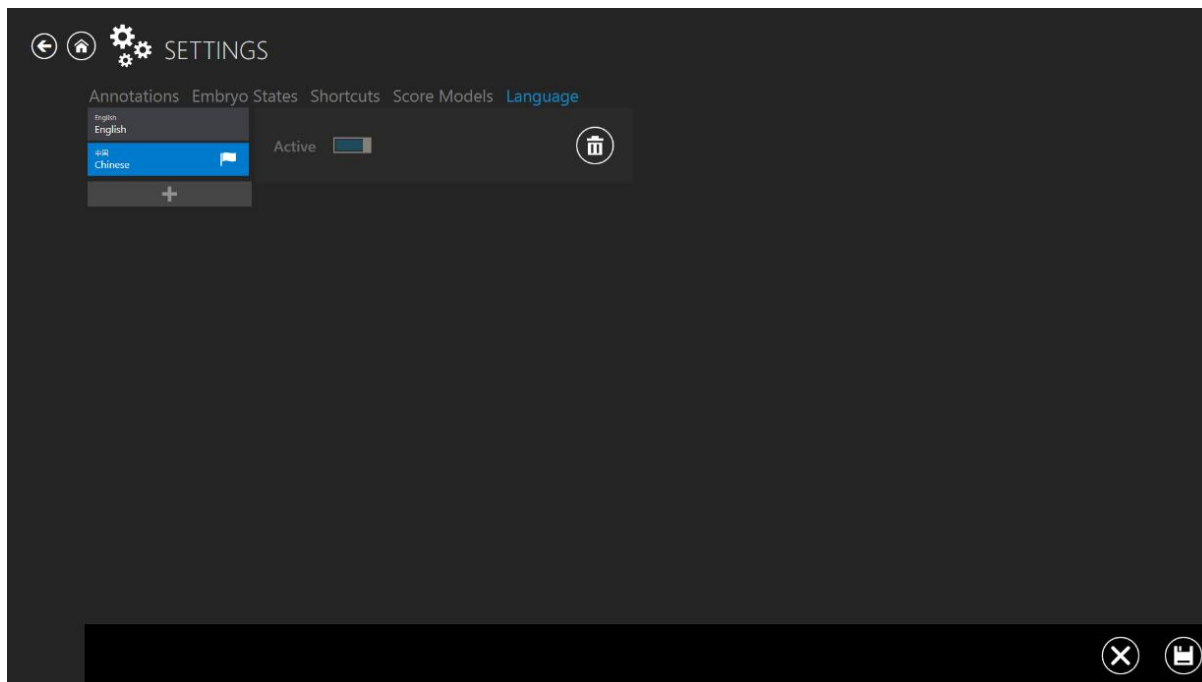


Figure 7.181 Additional language enabled

After saving the new language option the menu will appear in the language of choice. Additionally, a multilanguage dialog box will become available in the “Main view” for a more convenient place to choose between different languages.

 If the “Languages” submenu is left without saving the modifications, a dialogue box will appear informing the user about unsaved changes.

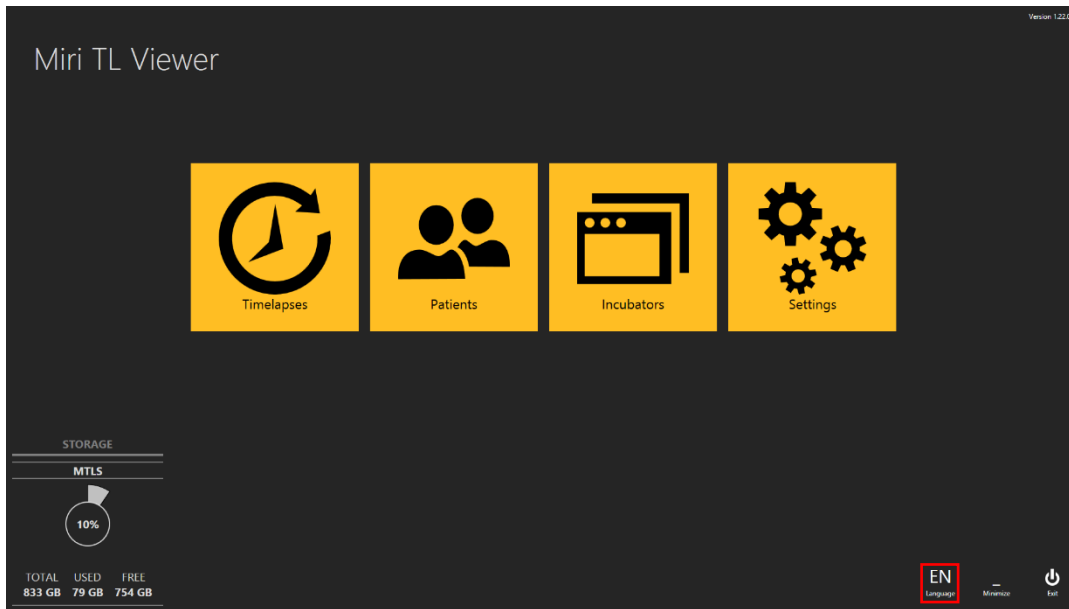


Figure 7.182 Main view with the multilanguage option

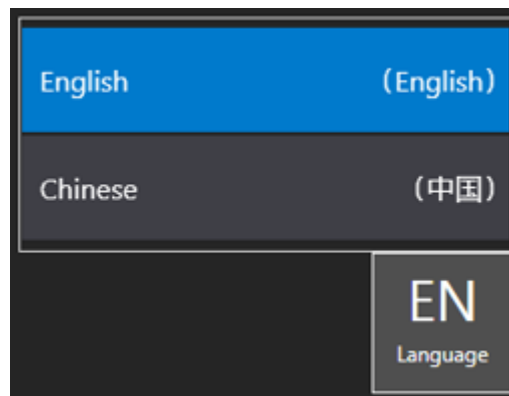


Figure 7.183 Multilanguage dialog box

8 Technical assistance

For more information, contact Esco Medical Technologies, UAB or the local Representative.

9 Data Management & Backup

9.1 Recommendations

To mitigate the risk of data loss due to hardware failure, file corruption, or unauthorized tampering, the user facility must implement the following data maintenance procedures.

1. **Data Backup**

The system automatically generates a backup of the patient and incubation databases on the local hard drive.

The system does **not** perform automated backups of the SQLite image databases.

Please contact Esco Medical service for detailed technical guidance on data storage and backup recommendations.

It is the responsibility of the user facility to periodically back up data to a **secure, external network location** (e.g., the provided Synology DiskStation network share, or the facility's network storage).

Esco Medical recommends performing backups daily or weekly, depending on the volume of clinical activity.

2. **Manual Export:**

Upon completion of a patient cycle, clinicians are strongly advised to export the image and/or video data generated by the MIRI® TL System and store them on a secure external network location.

3. **Storage Verification:**

Regularly monitor the available storage capacity on the Incubator's local drive and the primary storage to prevent "Disk Full" errors, which may result in image acquisition stopping or inability to create new time-lapses.



Please contact Esco Medical service for technical guidance on increasing storage capacity.



The MIRI® TL system does not feature automated off-device redundancy for active timelapse image data. In the event of a critical hardware failure of the Incubator's internal storage before data synchronization is complete, data loss may occur. Adherence to manual backup protocols is essential to ensure high availability and clinical continuity.

9.2 MIRI® TL API for Data Exchange

The MIRI® TL Application Programming Interface (API), developed by Esco Medical Technologies, is available as an optional software component for the MIRI® TL System. It is intended to facilitate data exchange between the MIRI® TL System and third-party software.

The API is not installed by default; installation and configuration are performed only upon separate request from the customer. Use of the API requires that the customer or their IT/vendor develops and maintains a dedicated client application that communicates with the API within the clinic's validated network.