ESCO MEDICAL

USER MANUAL

MIRI® TL family`s multiroom IVF incubators Viewer Software

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CERTIFIED INCUBATION

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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.

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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, CO_2 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® TL6 and MIRI® TL12 multiroom IVF incubator are a CO_2/O_2 incubators with timelapse capability. In the MIRI® TL6 it possible to incubate up to 84 embryos, whereas MIRI® TL12 – up to 168 embryos. The multiroom IVF incubators can generate timelapse images and provide them to identify development quality and stages.

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 30s) 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 unit's electronics so it remains a truly separate validation system.

The multiroom IVF incubator has to be supplied with 100% CO_2 and 100% N_2 in order to be able to control the CO_2 and O_2 gas concentrations in the culture chambers.

A dual beam infrared CO_2 sensor with extremely low drift rates controls the CO_2 level. A chemical medical grade oxygen sensor controls the level of O_2.

Gas recovery time is less than 3 min after opening the lid. 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.

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 filter and through a HEPA filter. The UVC light has filters that inhibit any 185 nm radiation that would produce dangerous ozone. The VOC 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 CO_2 and 5 l/h N_2 in use.

For safety reasons the multiroom IVF incubator has a very complete gas control system that consists of: pressure regulator (preventing dangerous gas pressure problems), gas flow sensors (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 safe 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 unit.

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 timelapse movie.

The Software contains logging functions for a long-term data logging and storage. Web module enables the QC data to be transferred for off-site evaluation – by performing this, the manufacturer can provide a valuable service to the customers.

The user can plug any standard BNC pH probe to the unit 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.

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 derivates, 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 chose 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 1.21.0.0.

6 Installing the Software

The software is provided preinstalled on an AIO computer.

6.1 Requirements

The software is validated and tested to run under the Windows 8 or 10 operating system. It may run under previous versions of Windows, but the manufacturer cannot guarantee stability.

Requirements for MIRI® TL Viewer software:

- Intel i5, i7 or AMD FX at ≥ 3.0 GHz.
- 4GB RAM.
- 4GB Available Storage Space.
- 23" or 24" Full HD display with touch capabilities.
- Windows 8 or 10 (64-bit) Operating System.
- Gigabit Ethernet port.

Requirements for MIRI® TL Viewer-Server hybrid computer:

- Intel i7 processor with CPU benchmark rating of ≥ 8000.
- ≥ 8GB RAM.
- 256GB SSD Storage space for software.
- 1000 GB SSD Storage space for data storage.
- Windows 8 or 10 (64-bit) Operating System.
- At least 2 USB 3.0 (type A) or newer ports.
- HDMI-input port.
- Gigabit Ethernet port.

7 Running the Viewer

7.1 Start-up

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

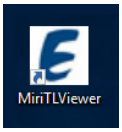


Figure 7.1 "MIRI® TL Viewer" icon on the desktop

By double-clicking on the icon, it will start the MIRI® TL Viewer application and show it on the main screen.

7.2 The main view

The main view shows 4 buttons:

- Timelapses (a list of the generated Timelapses).
- Patients (the patient's database).
- Multiroom IVF incubators (the 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 corner of the main MIRI® TL family`s multiroom IVF incubators Viewer screen, storage information is also provided to the user.

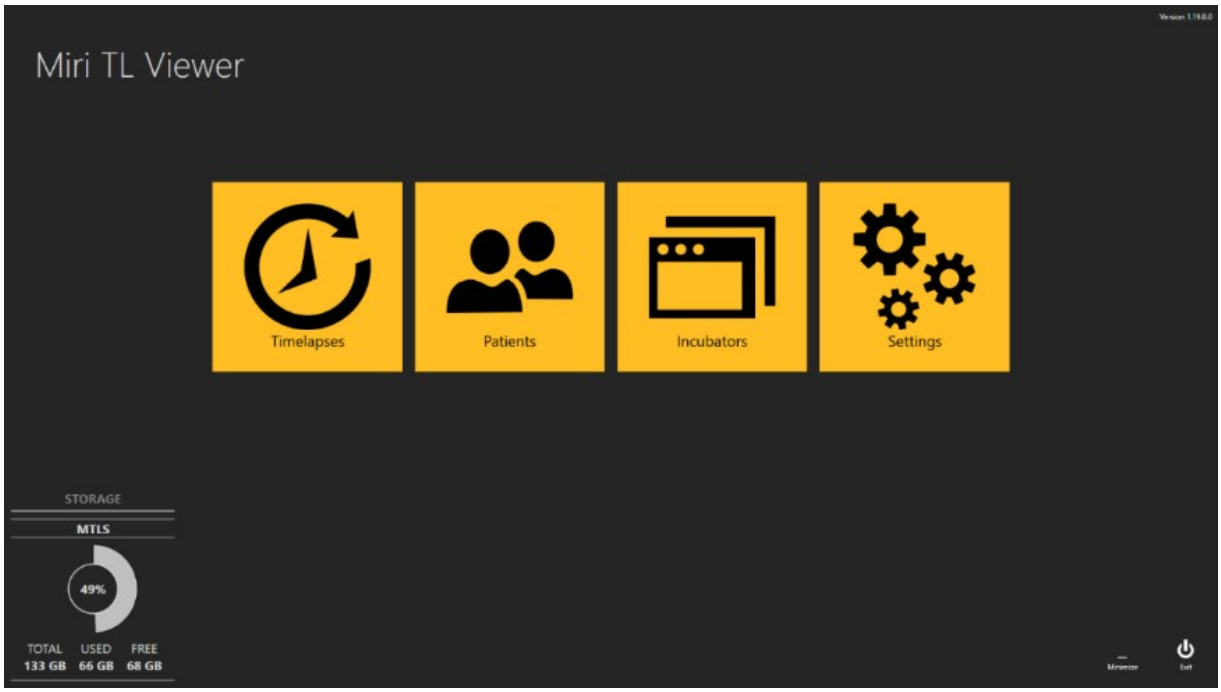
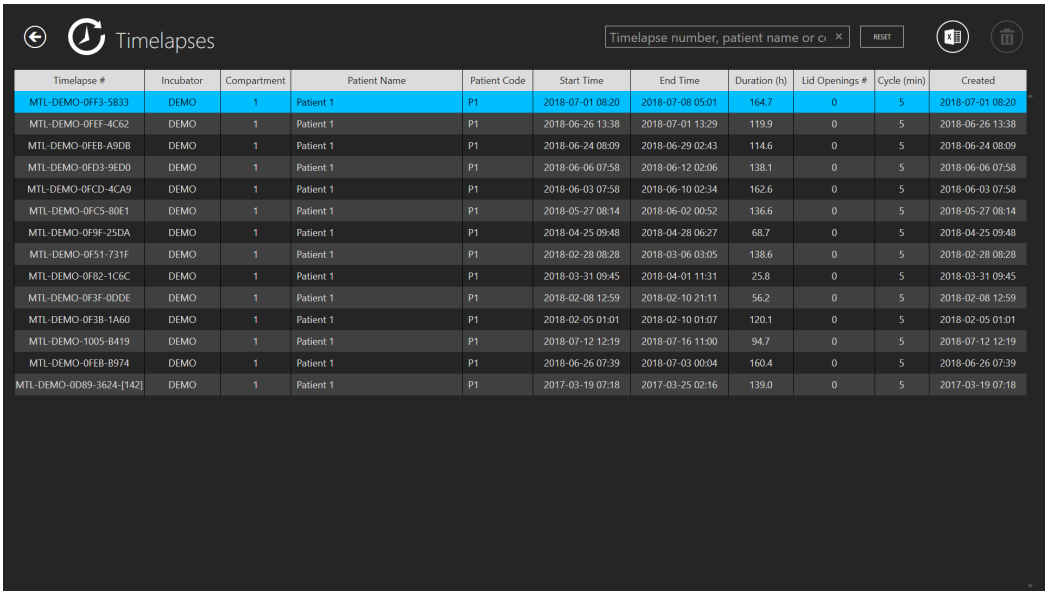


Figure 7.2 MIRI® TL6 and MIRI® TL12 multiroom IVF incubators Viewer main screen

7.3 Timelapses

7.3.1 Timelapse list view

Pressing the “Timelapses” button changes the view to the list of the timelapses generated on the attached MIRI® TL family`s multiroom IVF incubators. If more than one MIRI® TL6 or MIRI® TL12 multiroom IVF incubators are connected to the server, 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-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-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-0F82-1C6C	DEMO	1	Patient 1	P1	2018-03-31 09:45	2018-04-01 11:31	25.8	0	5	2018-03-31 09:45
MTL-DEMO-0F3F-0DDE	DEMO	1	Patient 1	P1	2018-02-08 12:59	2018-02-10 21:11	56.2	0	5	2018-02-08 12:59
MTL-DEMO-0F3B-1A60	DEMO	1	Patient 1	P1	2018-02-05 01:01	2018-02-10 01:07	120.1	0	5	2018-02-05 01:01
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”.

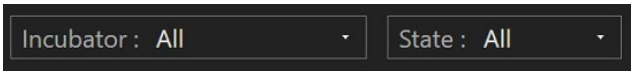


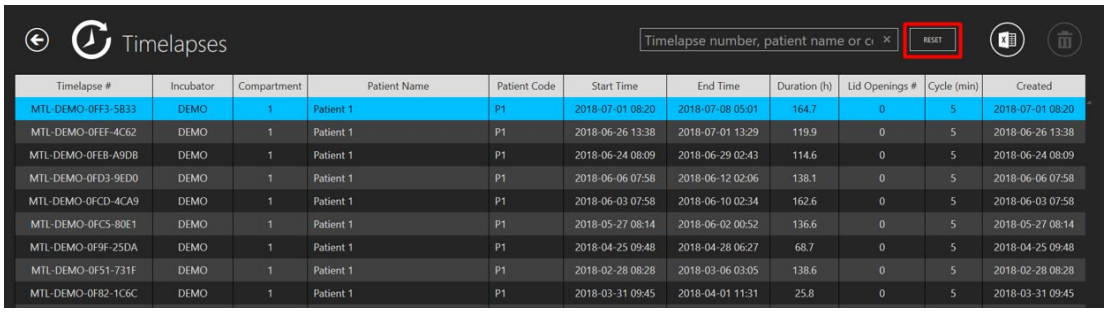
Figure 7.4 Filter function options

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

Figure 7.5 Search function

In a default mode, the view will list all timelapses arranged according to the treatment number (a counter that counts from the 1st timelapse to the current and always counts one up when the new timelapse is started).

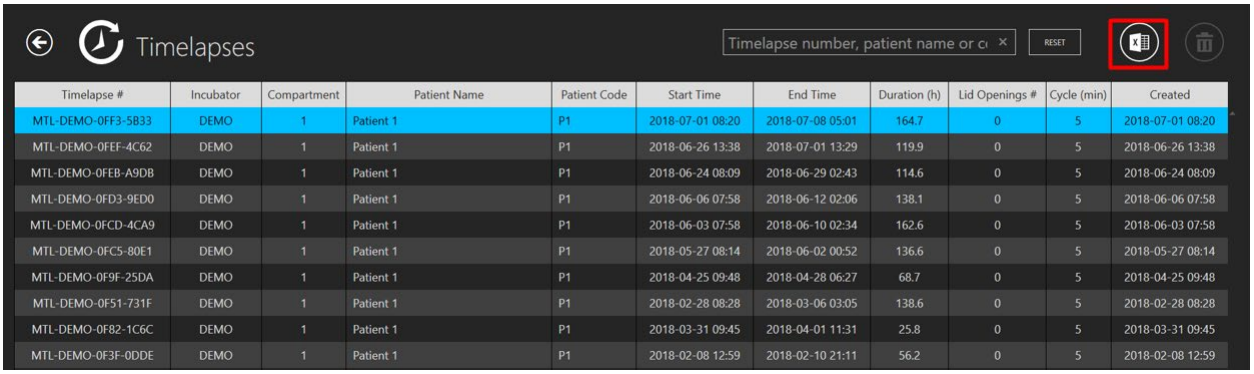
The “Reset” button will reset all selected filters.



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-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-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-0F82-1C6C	DEMO	1	Patient 1	P1	2018-03-31 09:45	2018-04-01 11:31	25.8	0	5	2018-03-31 09:45

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.



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-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-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-0F82-1C6C	DEMO	1	Patient 1	P1	2018-03-31 09:45	2018-04-01 11:31	25.8	0	5	2018-03-31 09:45
MTL-DEMO-0F3F-0DDE	DEMO	1	Patient 1	P1	2018-02-08 12:59	2018-02-10 21:11	56.2	0	5	2018-02-08 12:59

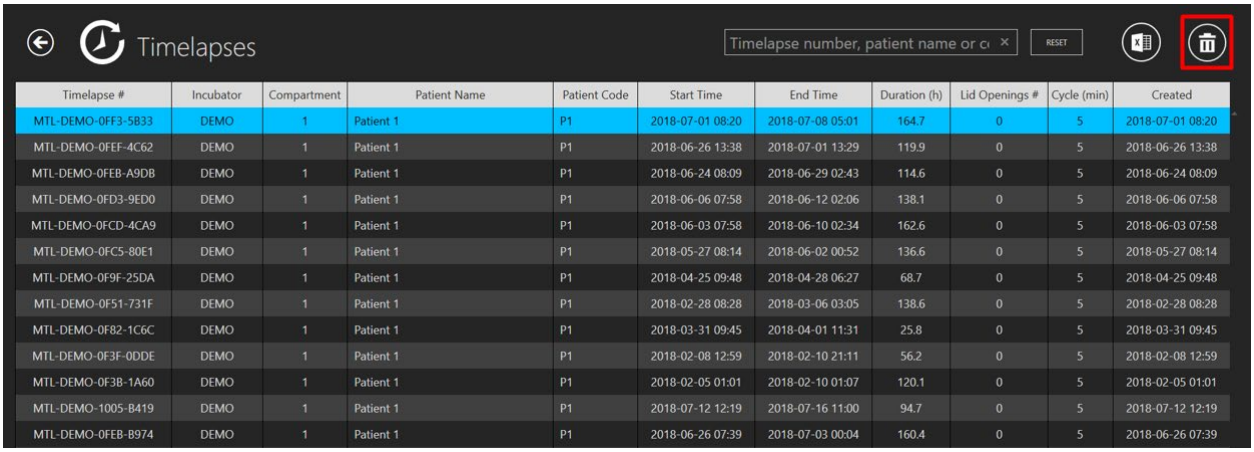
Figure 7.7 “Report” button

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.



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-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-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-0F82-1C6C	DEMO	1	Patient 1	P1	2018-03-31 09:45	2018-04-01 11:31	25.8	0	5	2018-03-31 09:45
MTL-DEMO-0F3F-0DDE	DEMO	1	Patient 1	P1	2018-02-08 12:59	2018-02-10 21:11	56.2	0	5	2018-02-08 12:59
MTL-DEMO-0F3B-1A60	DEMO	1	Patient 1	P1	2018-02-05 01:01	2018-02-10 01:07	120.1	0	5	2018-02-05 01:01
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

Figure 7.9 “Delete” button

The timelapse view shows:

- Timelapse number (unique timelapse identifier).
- Multiroom IVF incubator (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 7.10 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.

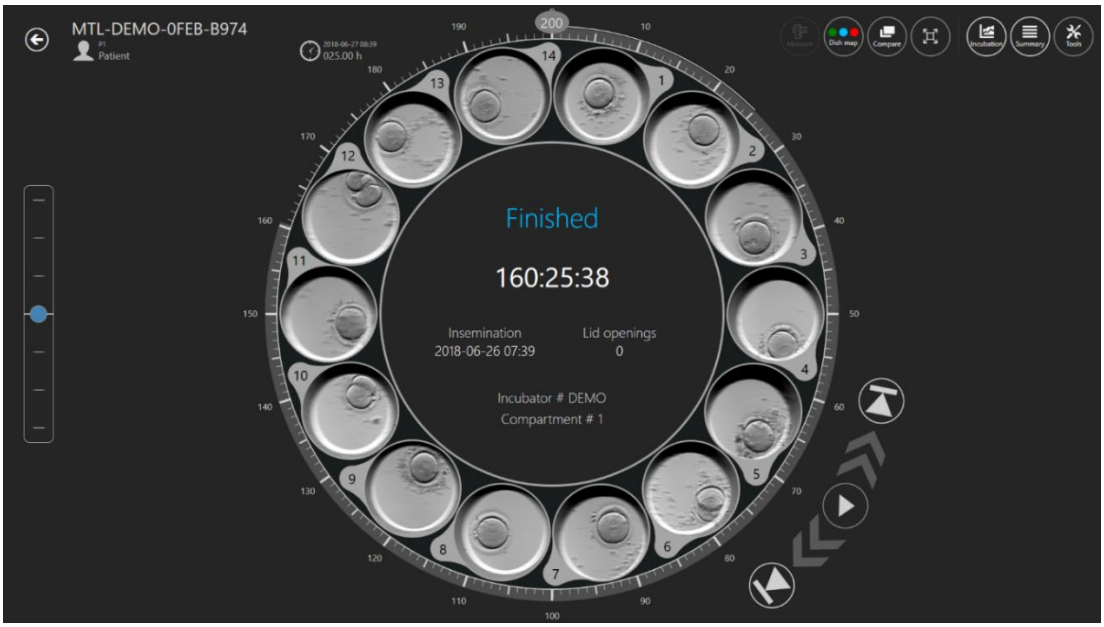


Figure 7.11 The timelapse view of a specific patient

The view contains the 14 wells of one single CultureCoin® dish. Sometimes the well can be displayed as inactive (see Figure 7.12), and the user will not be able to select it. In order to select specific activate or inactivate a specific well, please refer to the "User manual of MIRI TL family's multiroom IVF incubators", section 20.1.5 "Manual calibration of the well position".

Figure 7.12 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 Timelapse view, there is a focal plane shifter.

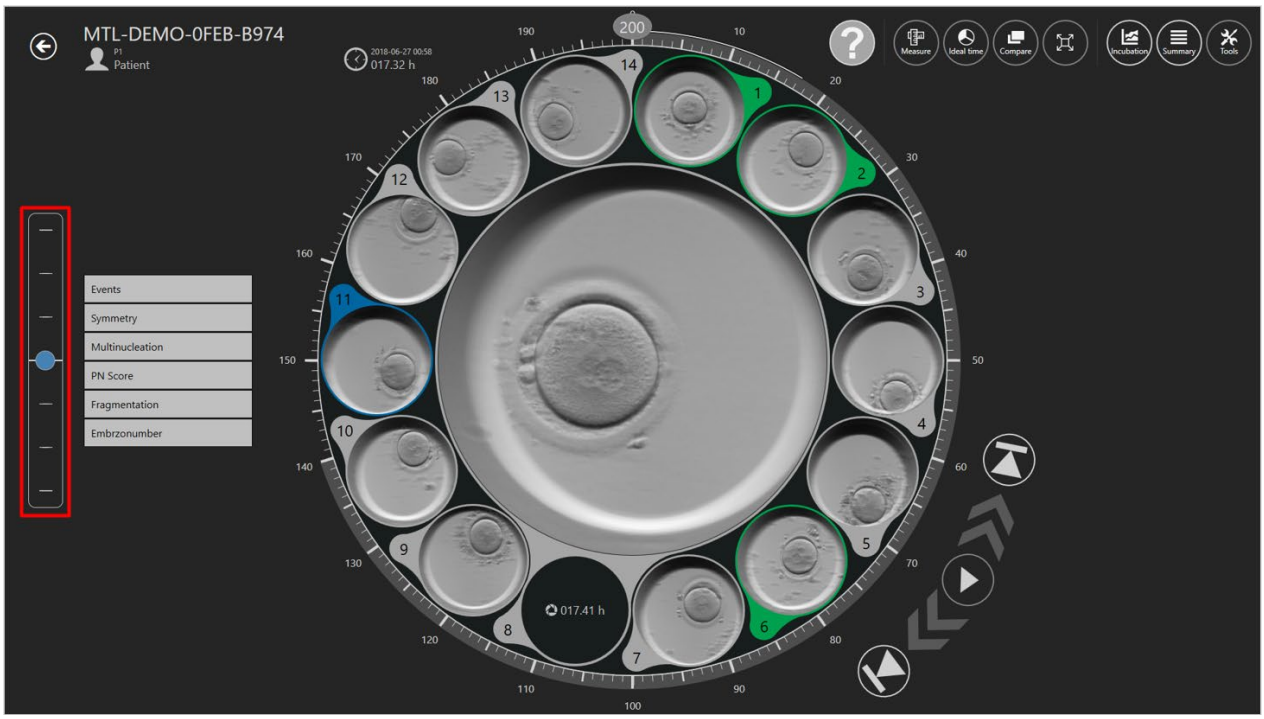


Figure 7.13 Focal plane shifter

It will have 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.

To the bottom right, near the main revolver view, 5 video player controls are located. They enable the user to move through the film, pause it, hit play or jump to the start or the end of it.

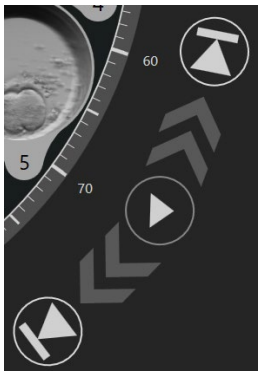


Figure 7.14 Video player controls

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 left of the revolver view, near the 13th well.

Figure 7.15 Selected time

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 main view. The software will show the square symbol and the specific time when the timelapse was stopped.

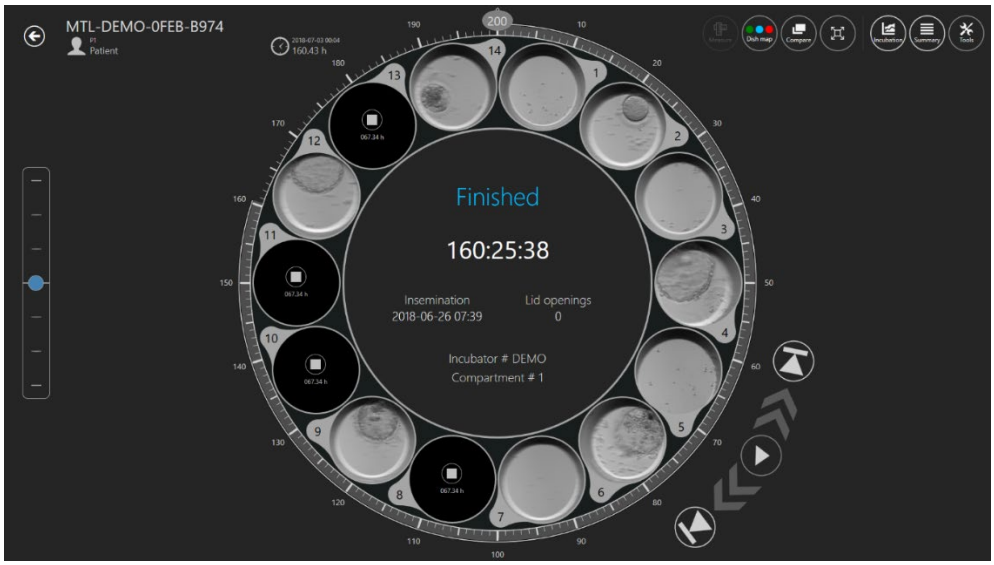


Figure 7.16 The timelapse view of a specific patient with 4 stopped timelapses

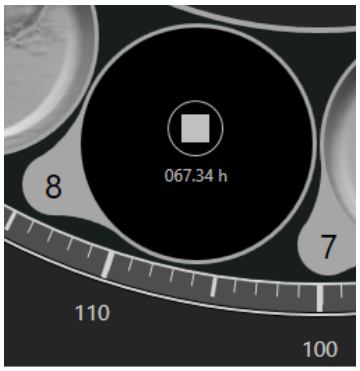


Figure 7.17 The view of the timelapse, which was stopped at 67.34h

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 annotation system. It is structured around "Events" located in the menu to the left of the revolver wheel.

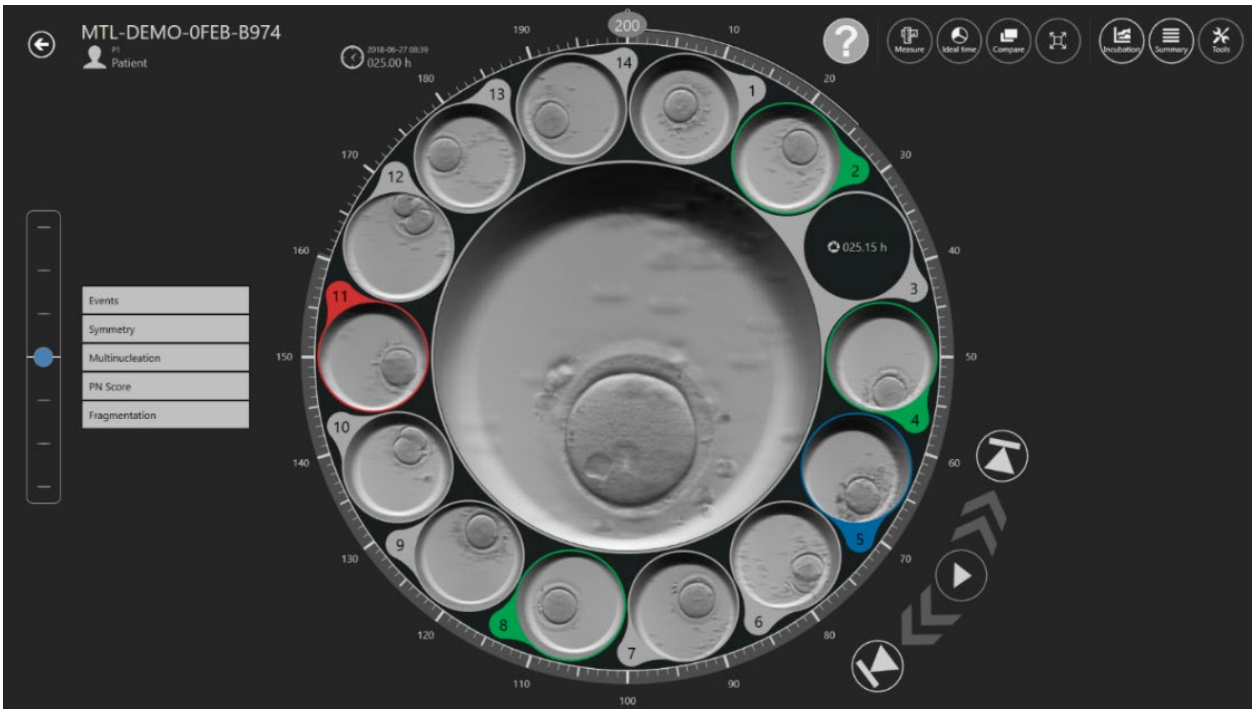


Figure 7.18 Timelapse annotation's view

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.

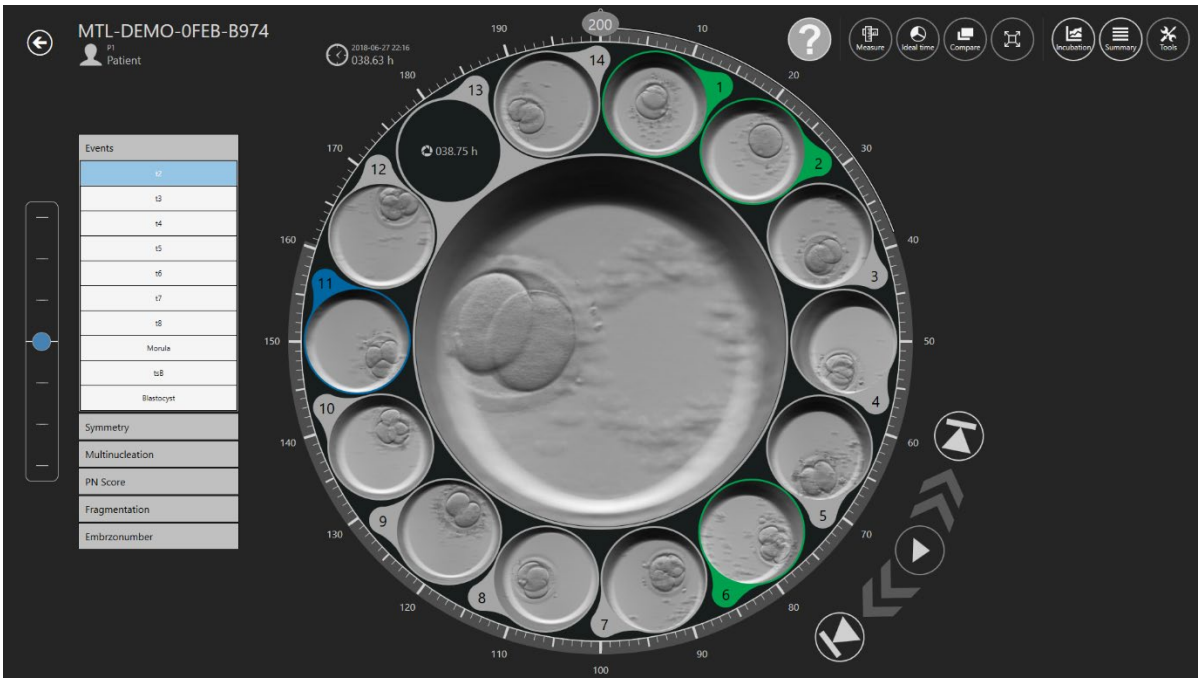


Figure 7.19 The view before adding the new event

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.

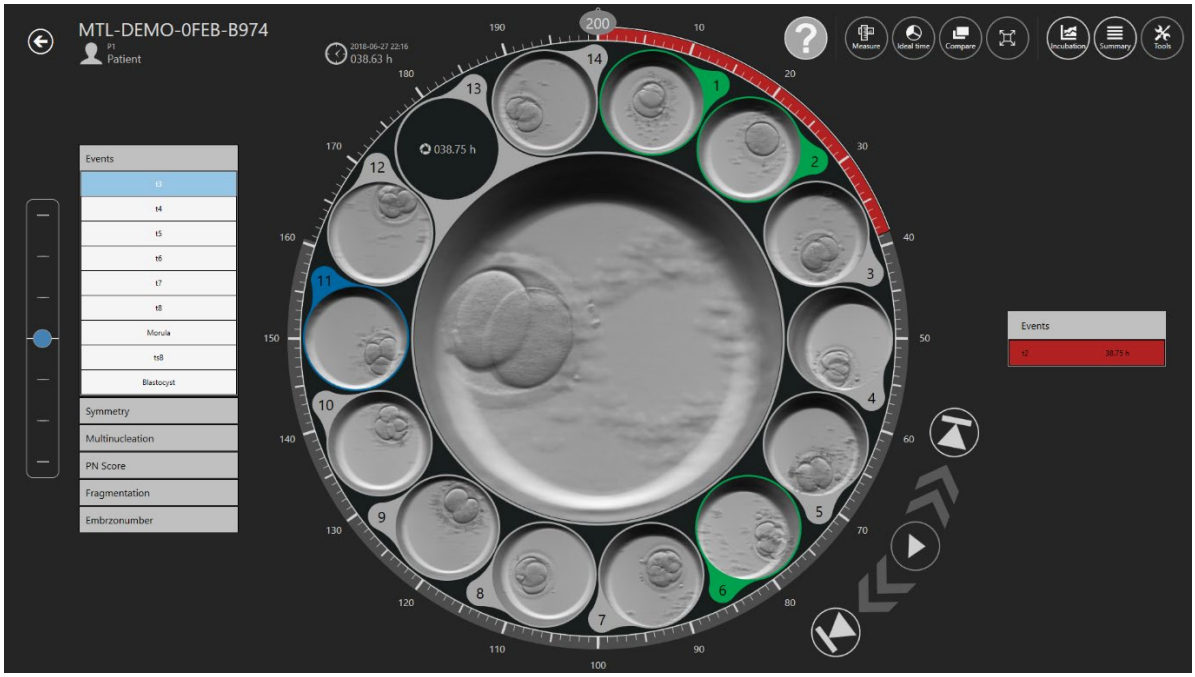


Figure 7.20 The view after adding the new event

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 Annotations" section of the User Manual for more details).

In the default form the annotation menu contains (see Figure 7.21):

- 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).

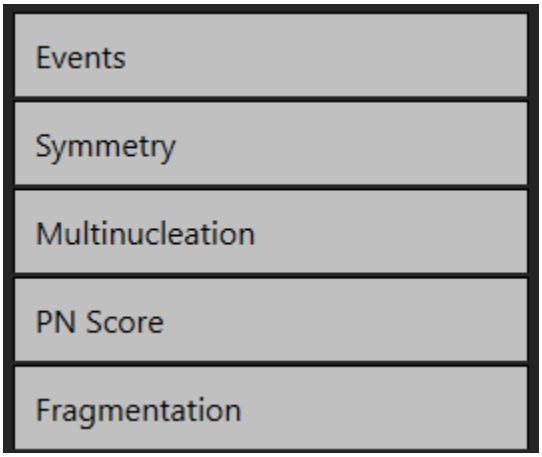
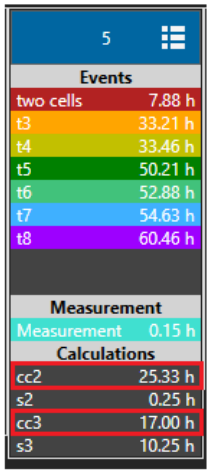


Figure 7.21 The annotation menu

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.



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

ANNOTATION GROUP	NAME	TIME
Calculations	cc2	25.33h
	s2	0.25h
	cc3	17h
	s3	10.25h

Figure 7.22 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).

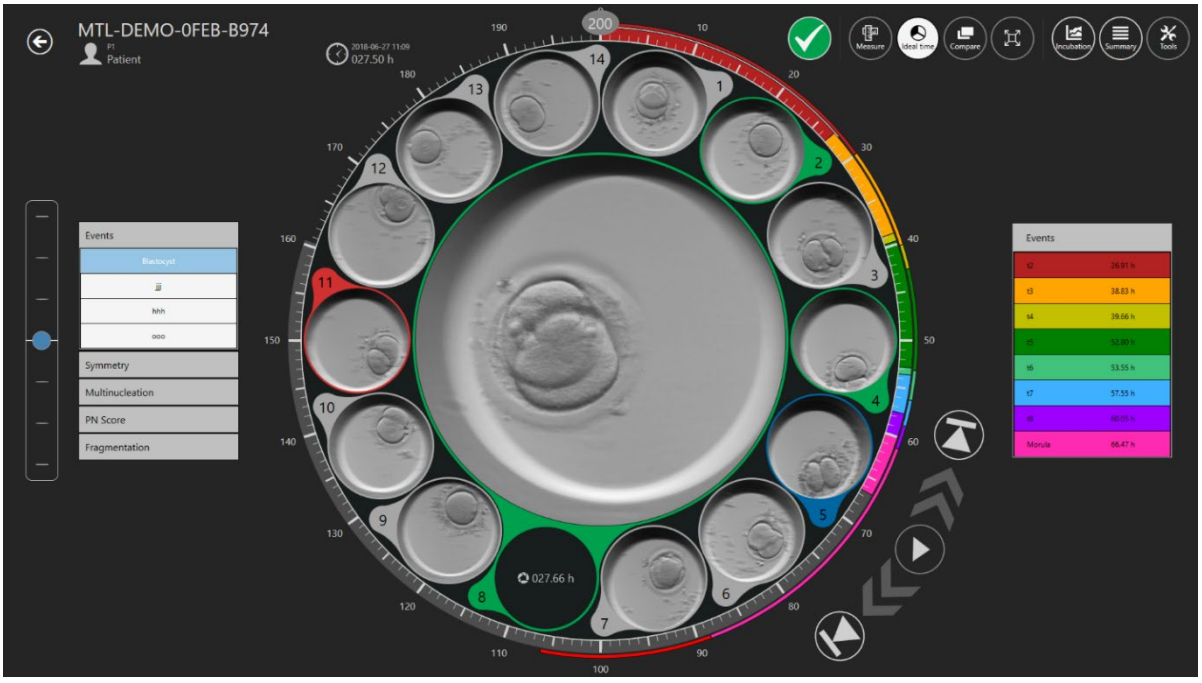


Figure 7.23 Selected "two cells" event annotation

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 7.24).

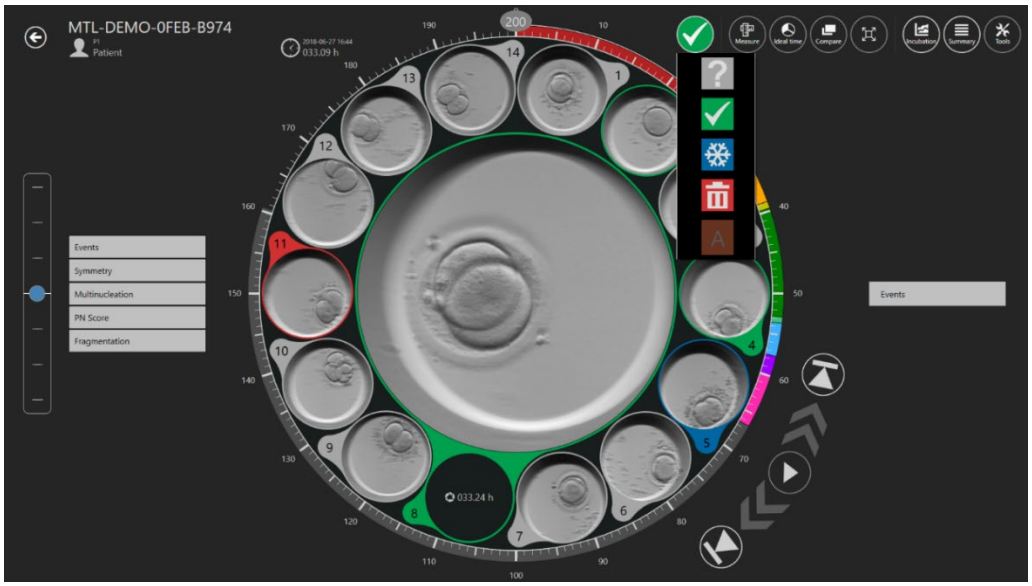


Figure 7.24 The embryo status selection

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.

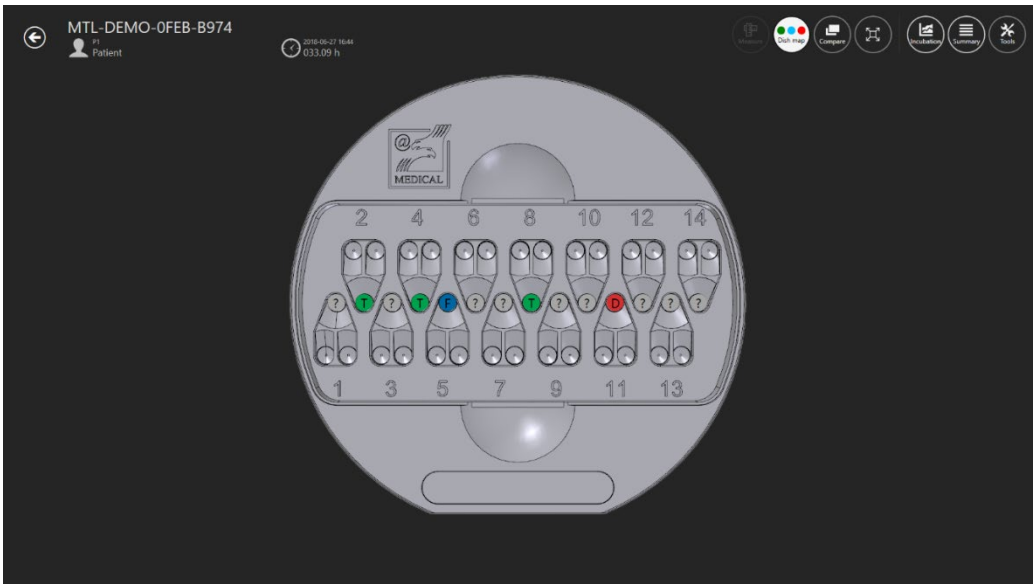


Figure 7.25 The dish map

7.3.2.2 Embryo measurement function

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

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

Figure 7.27 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.

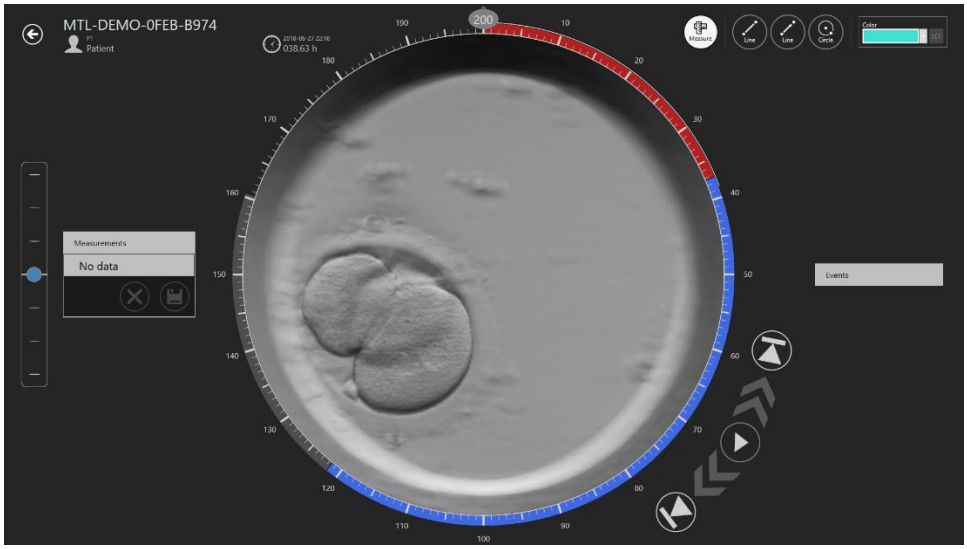


Figure 7.28 Full measurement view

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

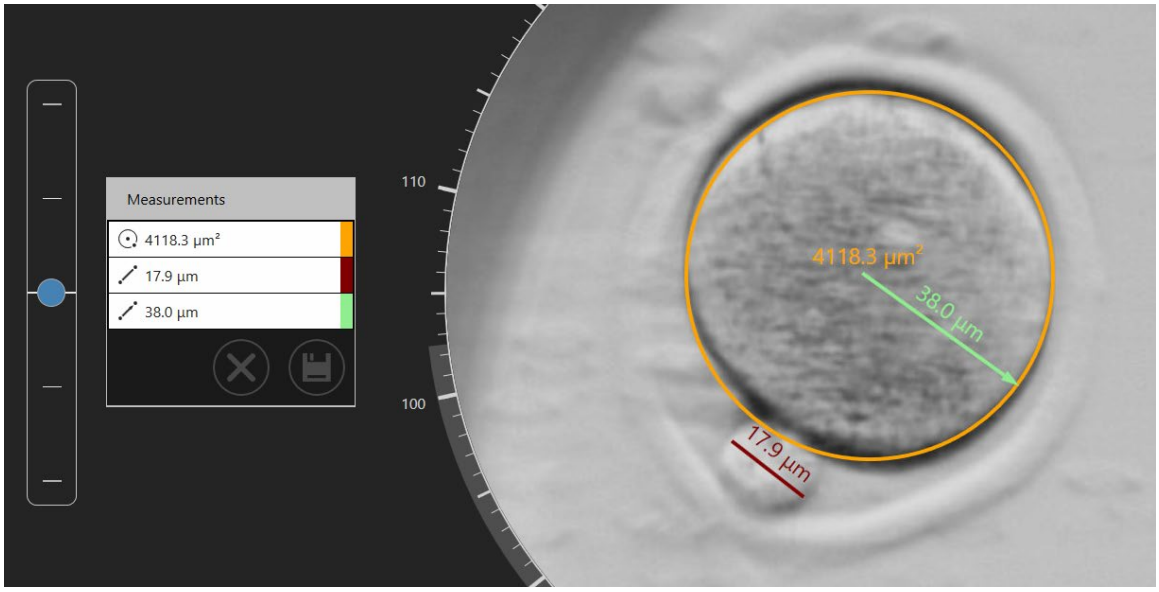


Figure 7.29 Added measurements on the timelapse image

There is a possibility to delete the unwanted measurement by double-clicking on it. Pressing on the "×" button will delete all the measurements.

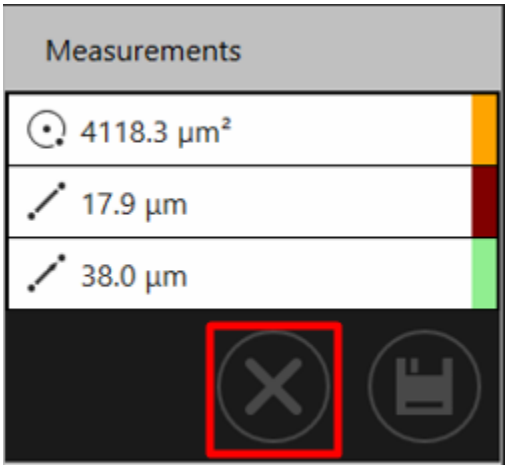


Figure 7.30 The "×" button

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. time slider is inactive) until the measurement changes are saved or canceled.

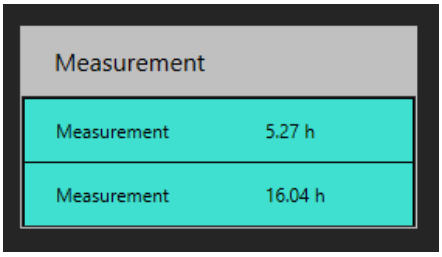


Figure 7.31 Example of measurements done at a specific time

7.3.2.3 The dish map

The "Dish map" button will open a view that shows the embryos' location in the CultureCoin® dish. It will also show the selected embryo state. The dish map can be printed or used during the transfer or handling of the embryos.

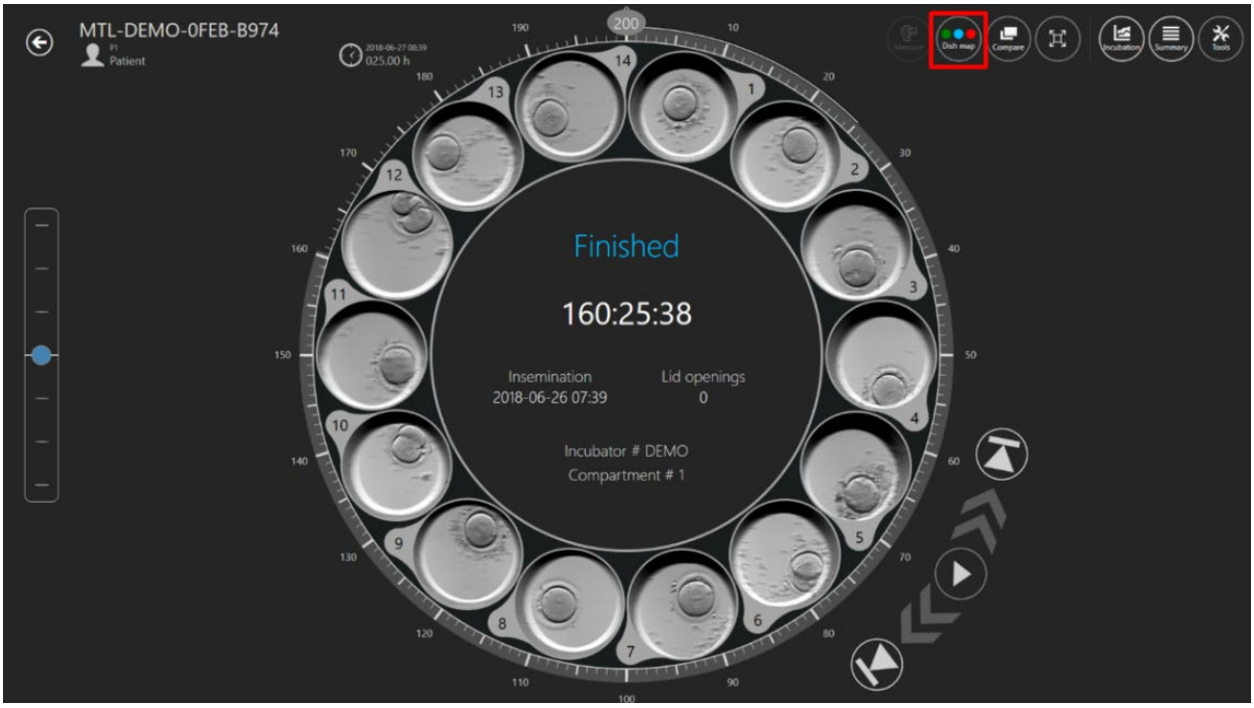


Figure 7.32 "Dish map" button

Make sure to deselect any well from the "Active area" to see the "Dish map" button.

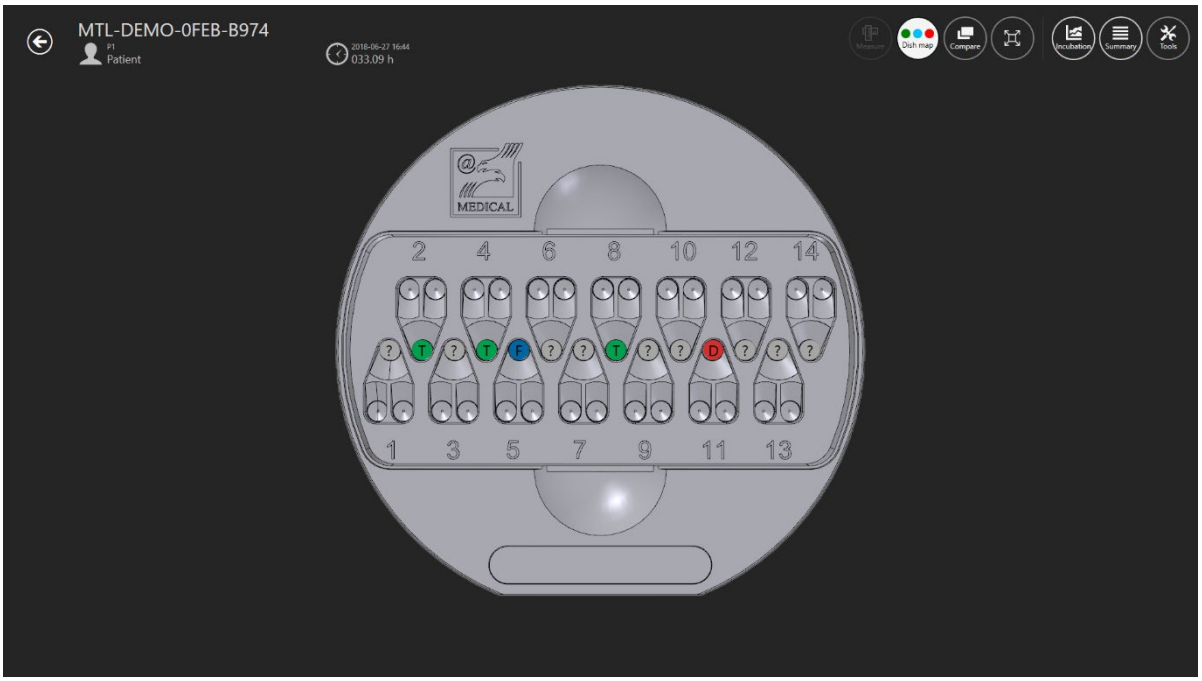


Figure 7.33 The dish map

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 7.34 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 7.35 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.

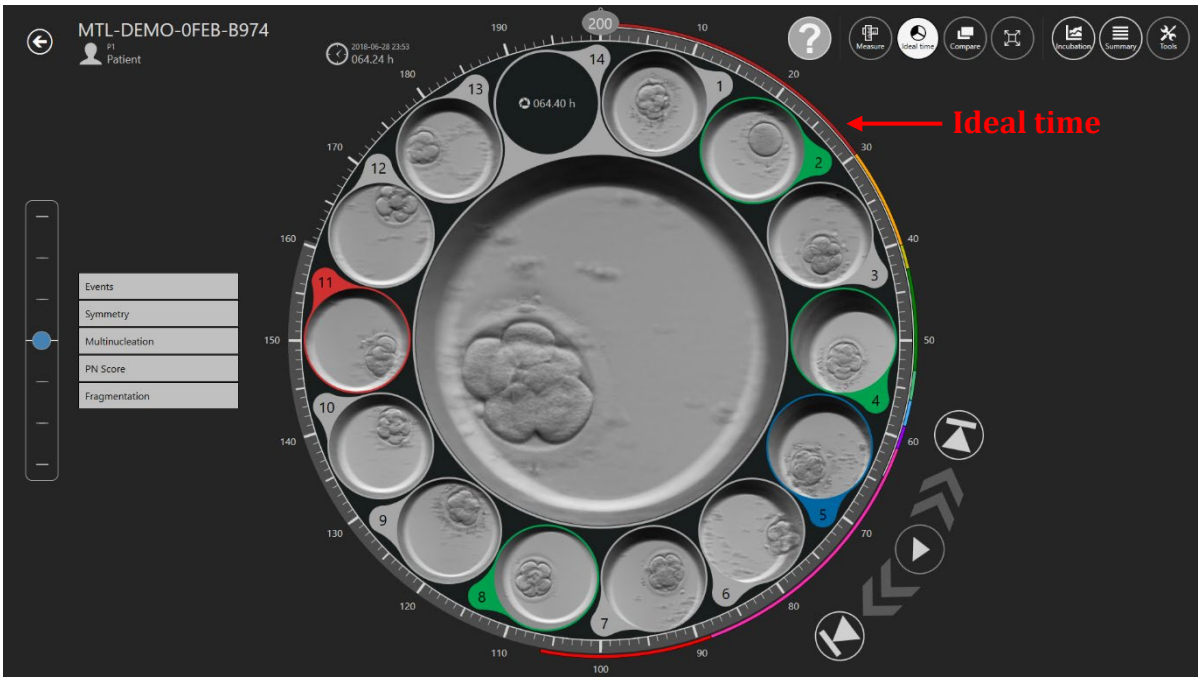


Figure 7.35 The ideal times shown around the revolver

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 Annotations" section of the User Manual for more guidance on how to change a specific event's ideal times.

7.3.2.5 Compare function

The "Compare" button makes it possible to maximize two embryos side by side for a more detailed comparison if it is difficult to make a selection.

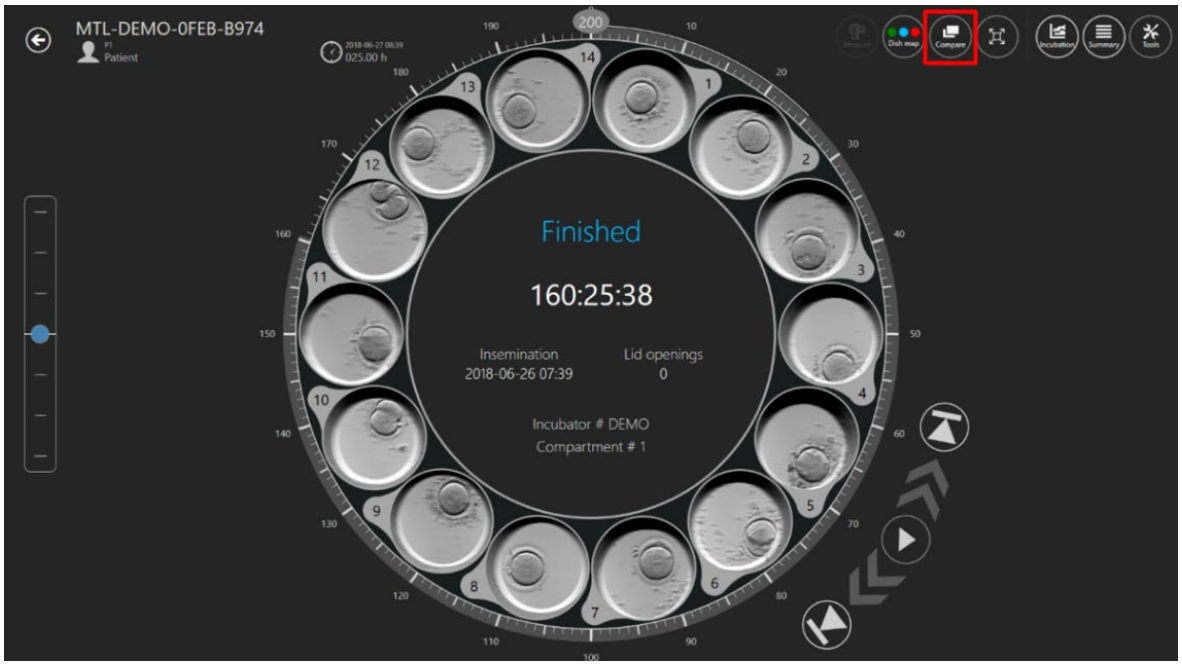


Figure 7.36 "Compare" button

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.

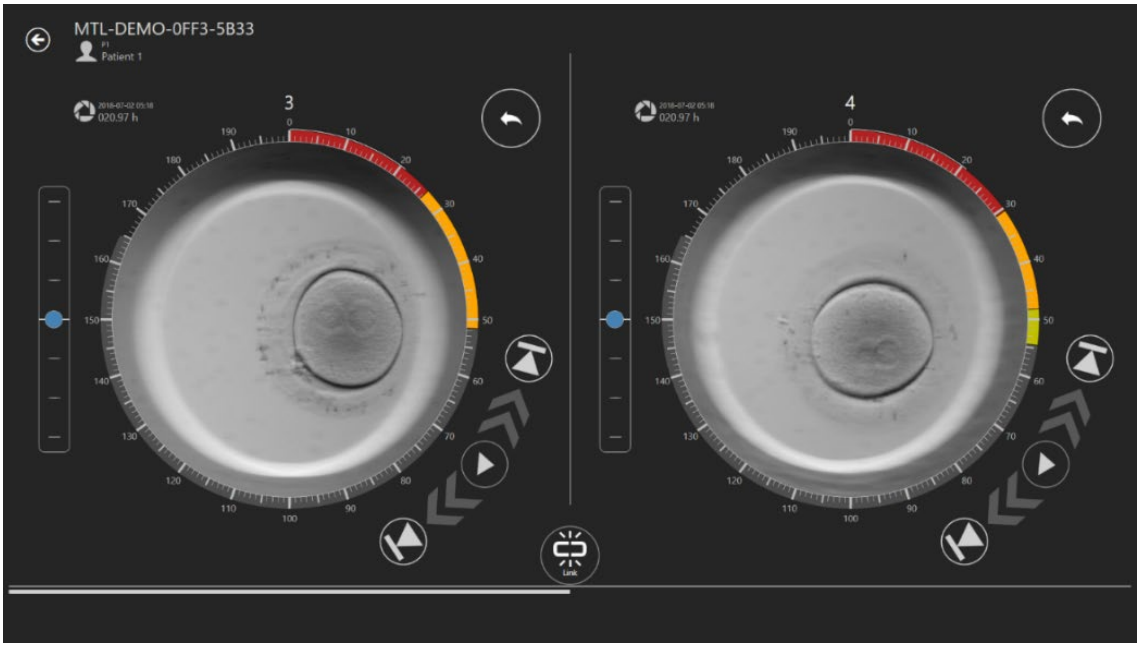


Figure 7.37 The independent "Compare" view

The two video players can be played independently or linked by pressing the "Link" button at the bottom of the screen.

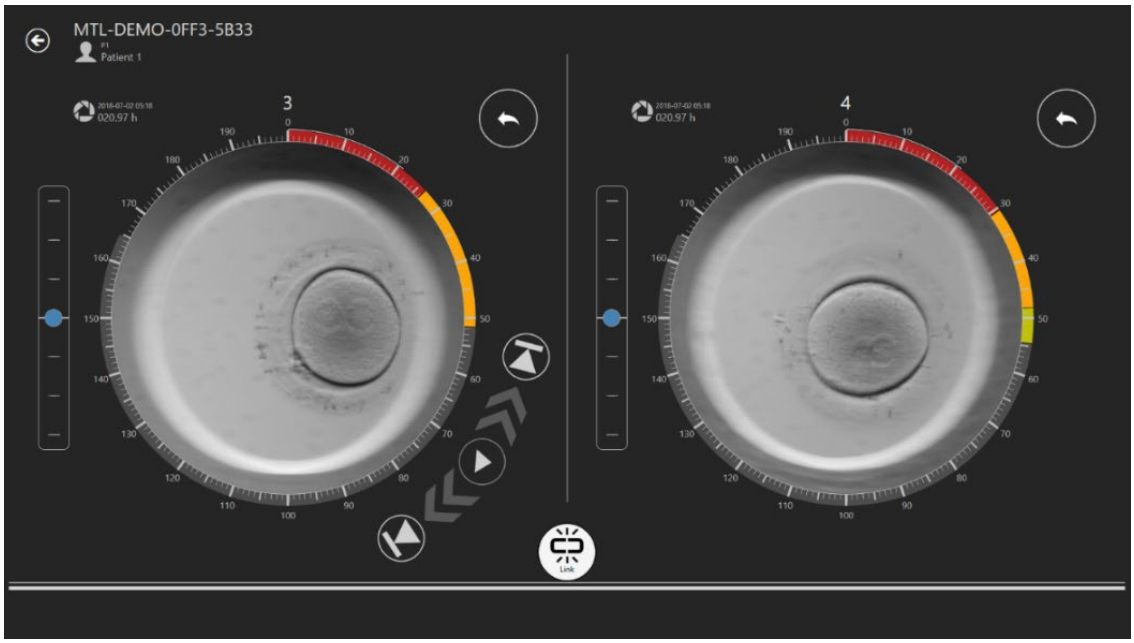


Figure 7.38 The linked "Compare" view

When two video players are linked, playback controls near the right well disappear.

7.3.2.6 Image maximization function

The "Maximize" button will place the selected well in the center of the revolver for a clearer visualization of a particular well.

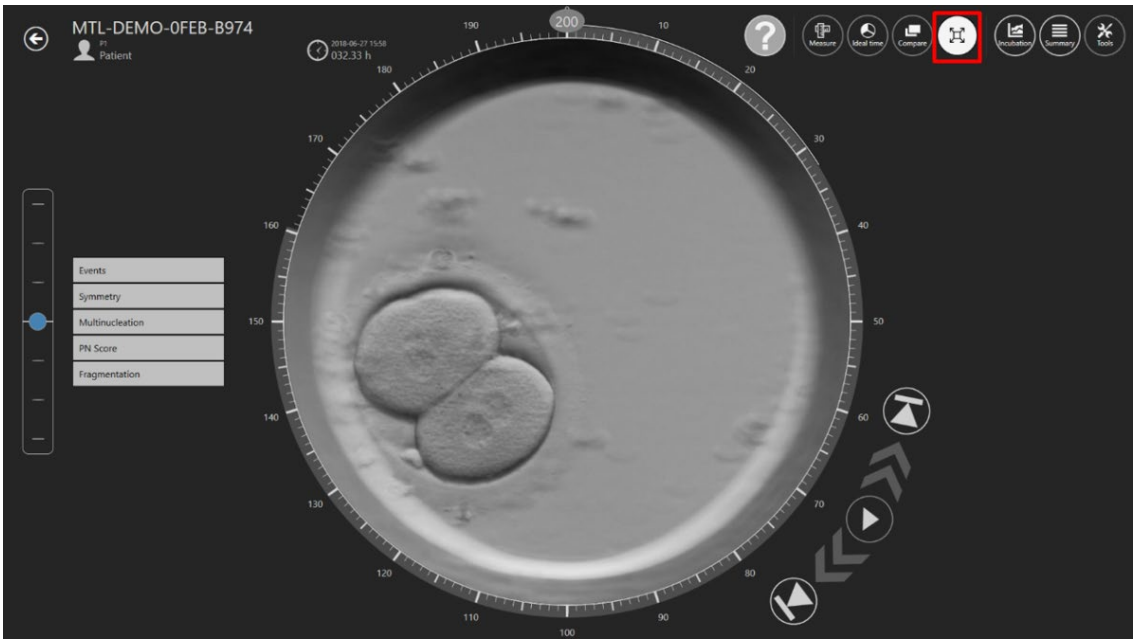


Figure 7.39 The "Maximize" button and the subsequent view

7.3.2.7 Incubation data logging function

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

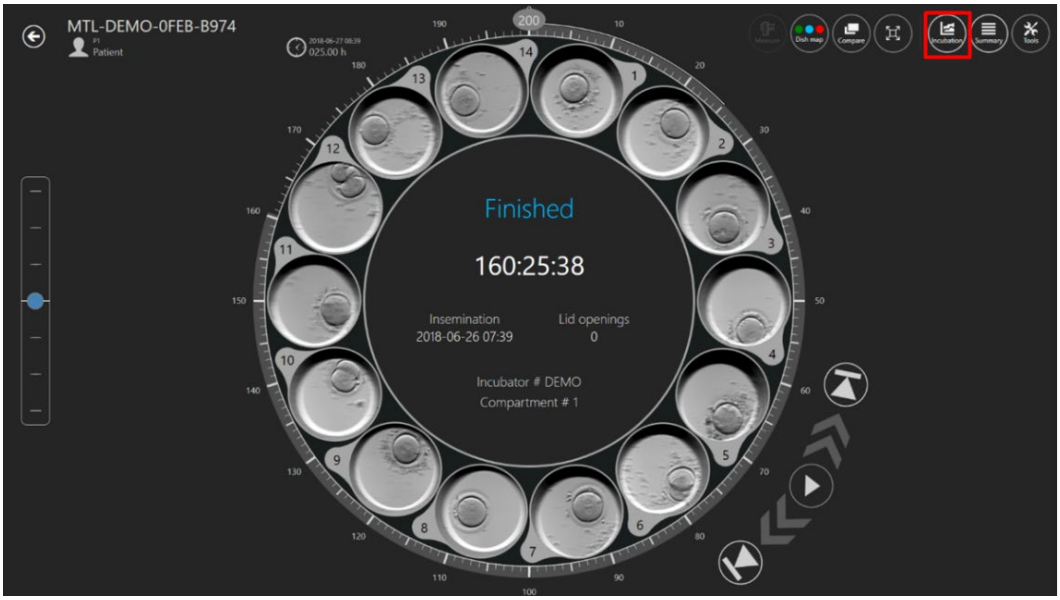


Figure 7.40 “Incubation” button

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

The user can select between temperature, CO_2, O_2 and alarms incubation data log in the top left corner.

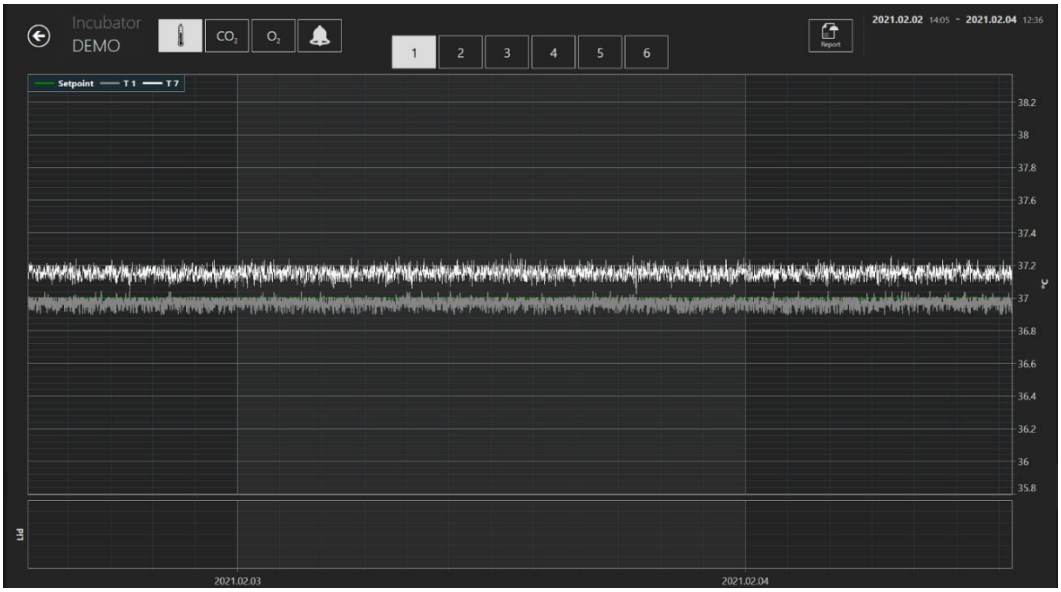


Figure 7.41 Temperature incubation view

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.

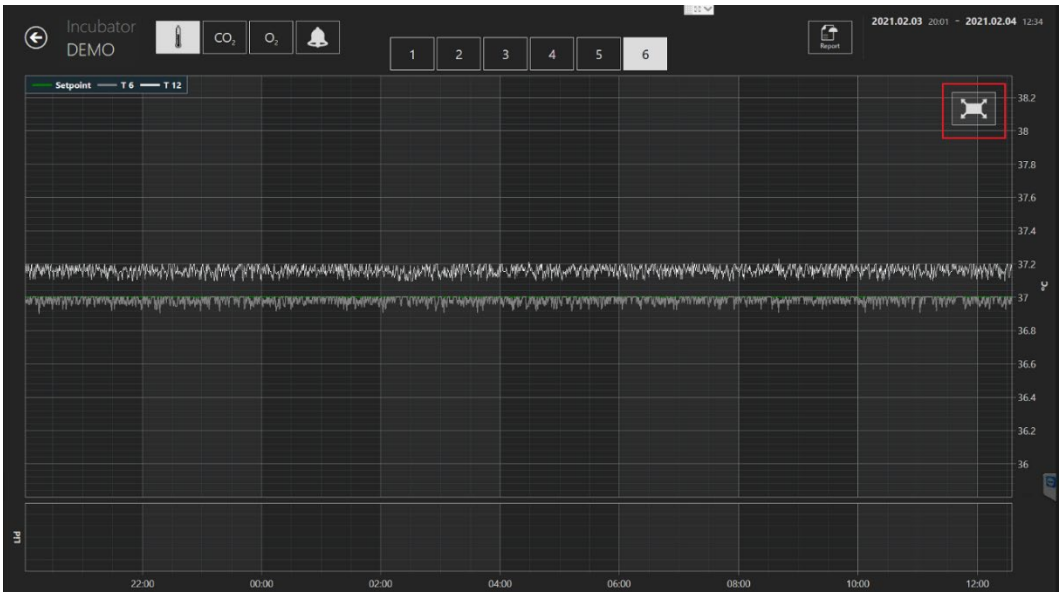


Figure 7.42 "Reset" button

Pressing the CO_2 button will shift from the temperature data view to the CO_2 gas data view.

Figure 7.43 The CO_2 data view

The user can see the historical data of CO_2 gas concentration setpoint, concentration, flow and pressure.

Pressing the O_2 button will shift from the CO_2 gas data view to the O_2 gas data view.

Figure 7.44 The O_2 data view

The user can see historical data of O_2 gas concentration setpoint, concentration, N_2 gas flow and pressure.

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

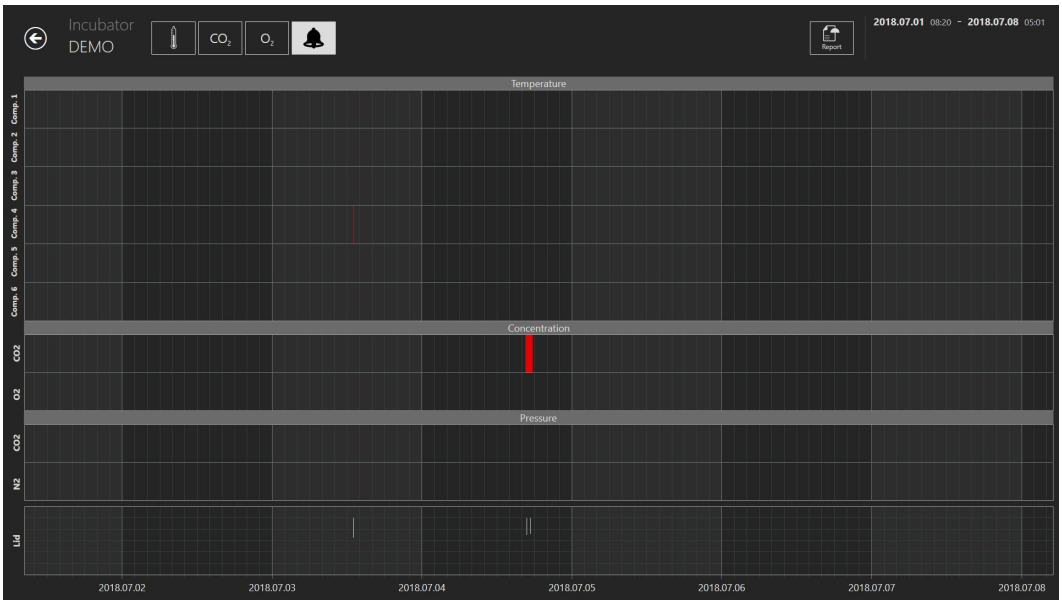


Figure 7.45 The graphical “alarm” view

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 function

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

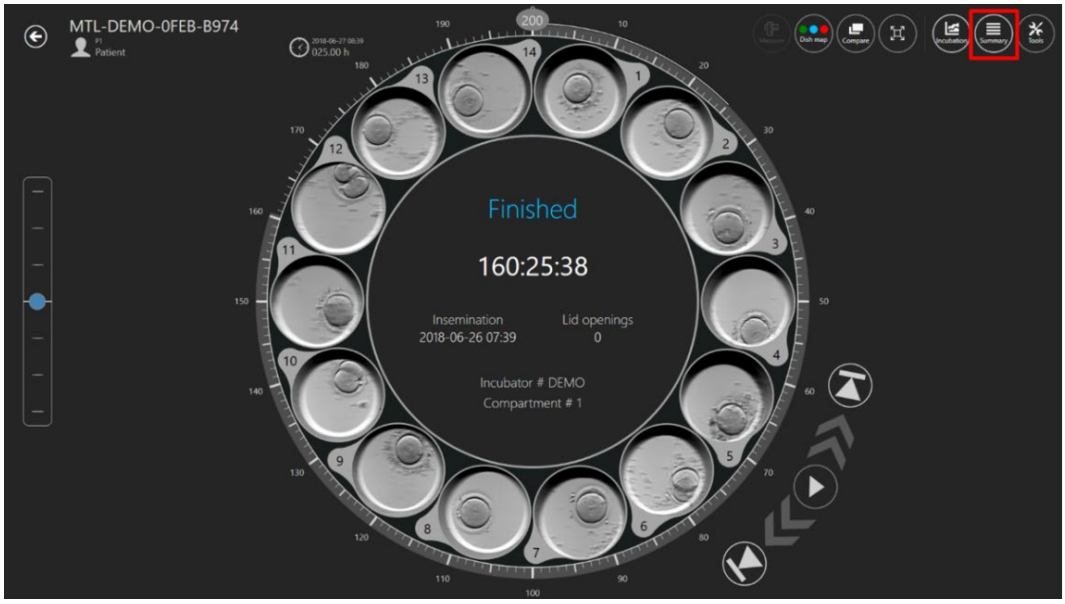


Figure 7.46 “Summary” button

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 7.47), 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 7.47 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 7.48 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.

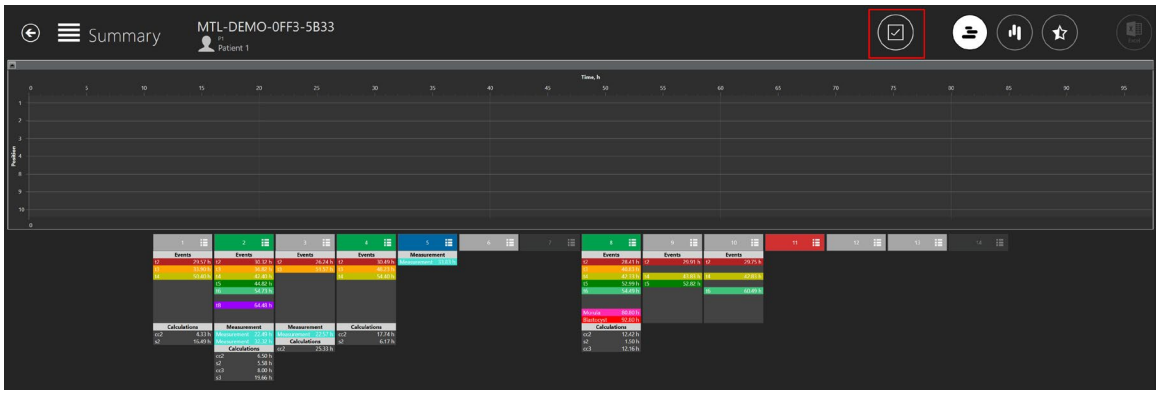


Figure 7.49 All deselected dish positions in a summary view

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 7.50 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).

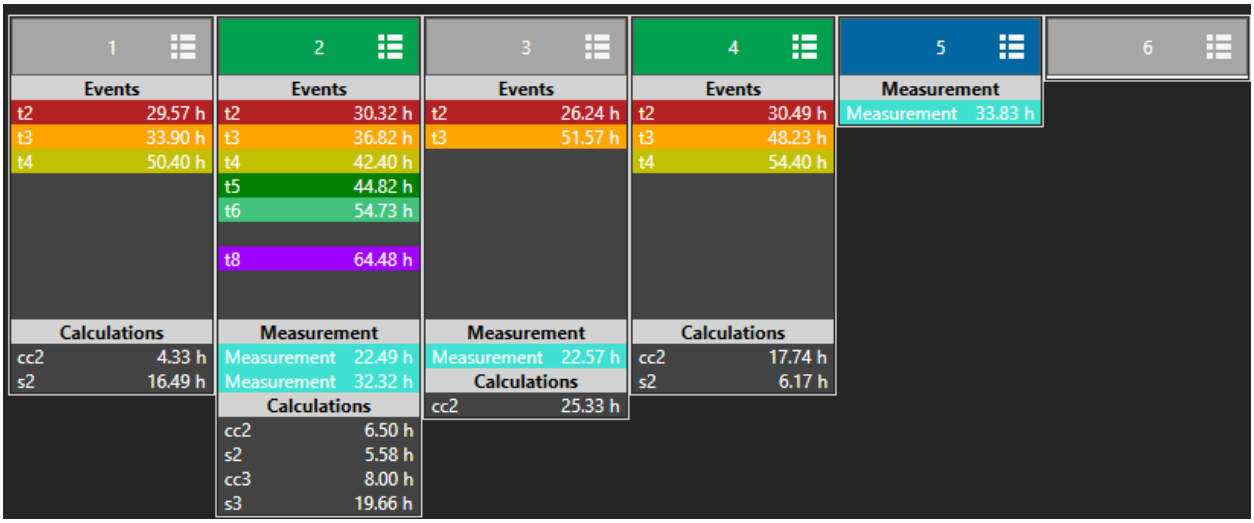


Figure 7.51 Event annotation are in alignment

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 7.52 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, in settings, is chosen to be inactive, 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 distinguish which deviations belong to which wells.

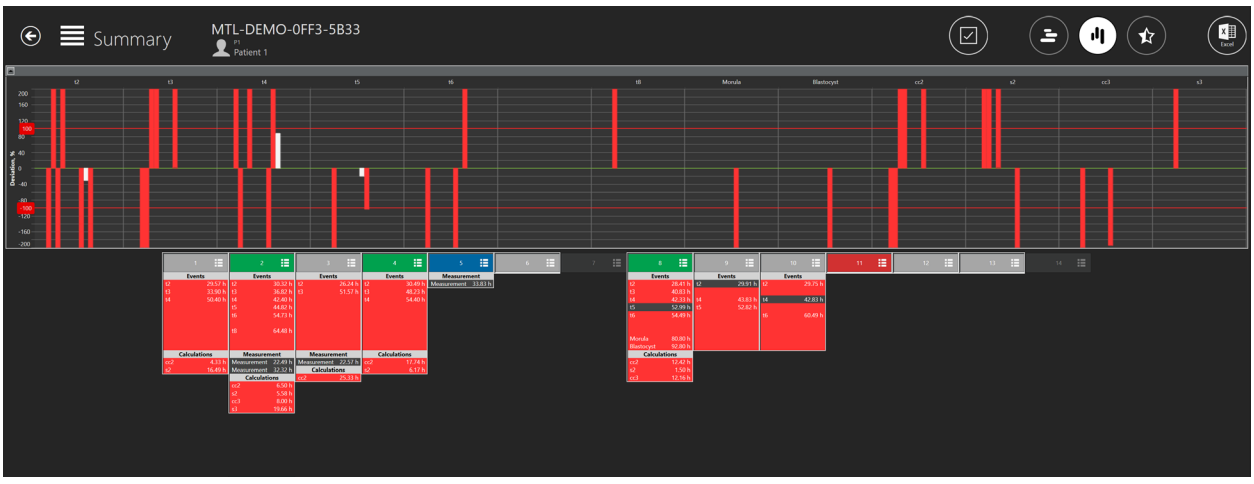


Figure 7.53 Vertical summary view

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).

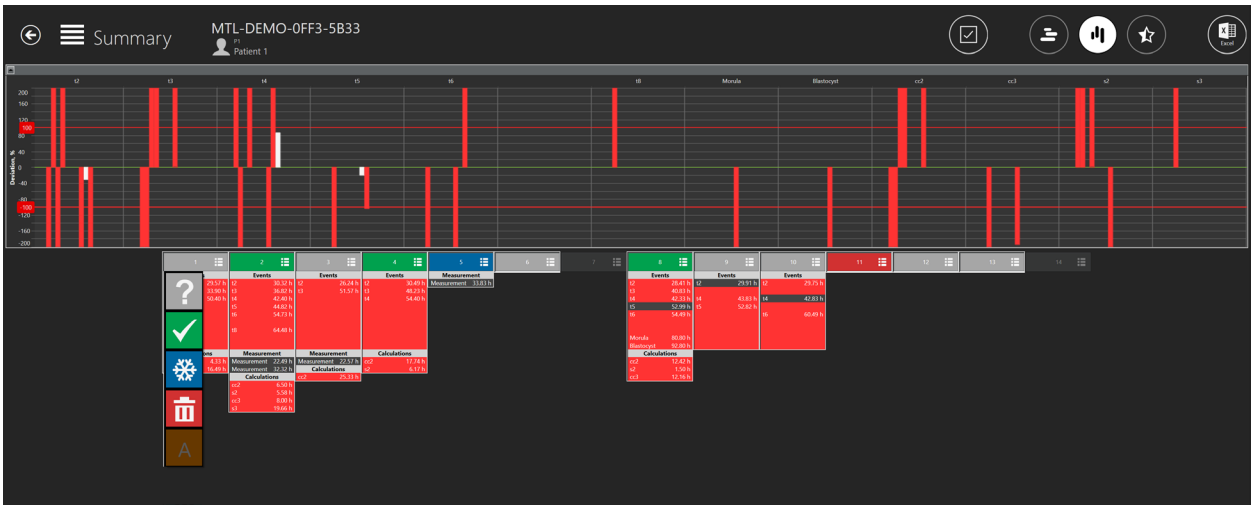


Figure 7.54 Dish status selection option in a horizontal summary view

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.

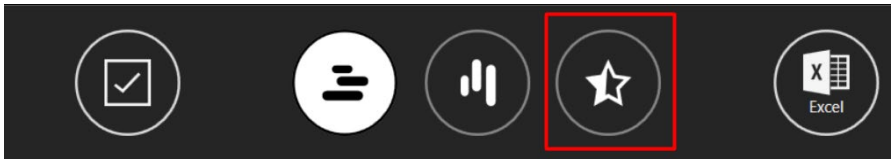


Figure 7.55 “Star” button in a summary view

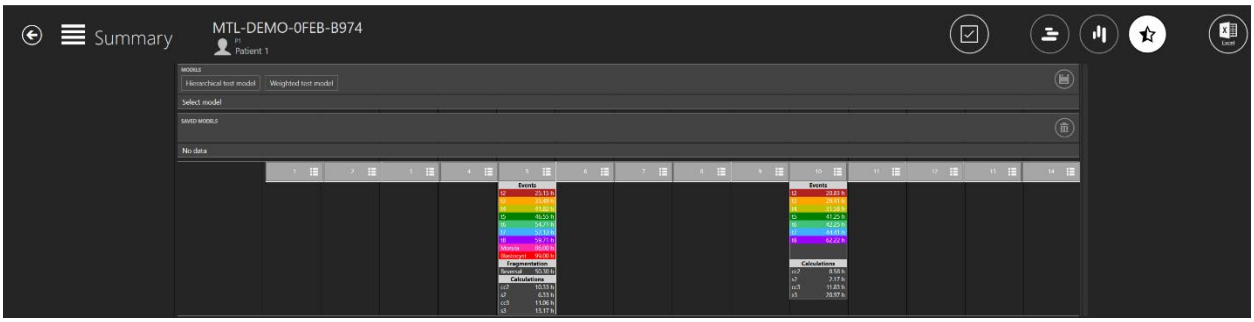


Figure 7.56 Embryo score model summary view

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.

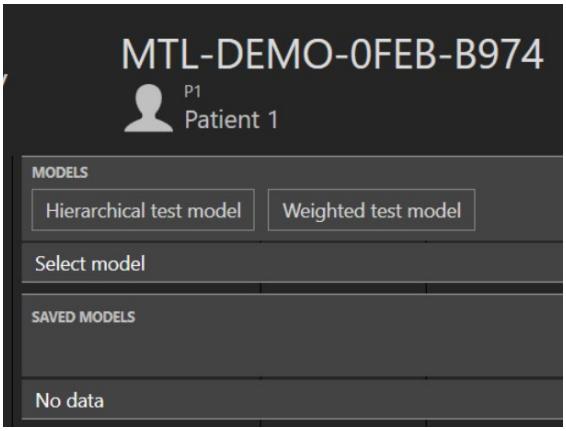


Figure 7.57 List of all created embryo score models

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

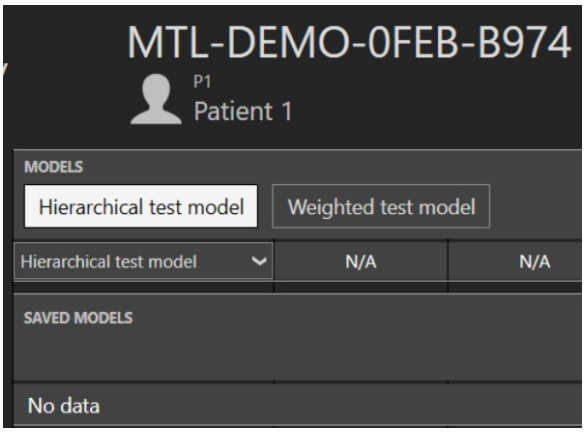


Figure 7.58 Selected "Hierarchical test model"

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

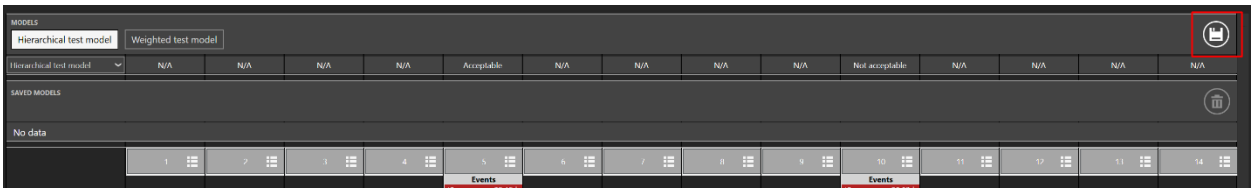


Figure 7.59 "Save" button

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

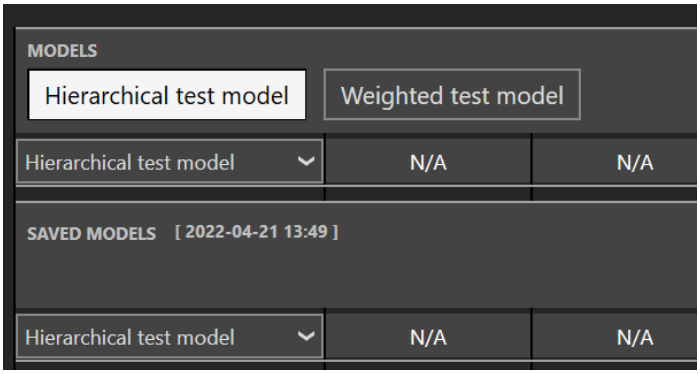


Figure 7.60 Hierarchical test model is now linked to a timelapse

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.

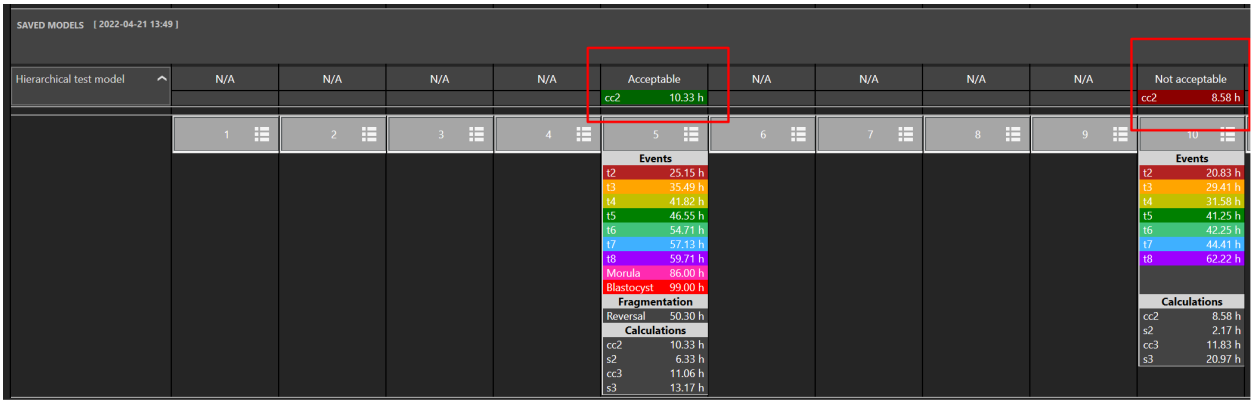


Figure 7.61 List of all conditional nodes that are created in the hierarchical score model

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 7.61 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.

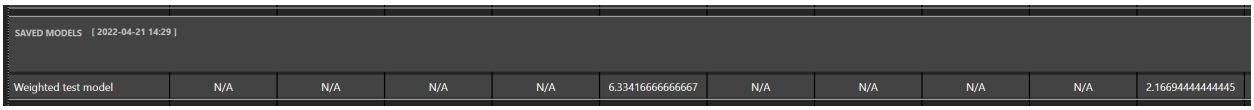


Figure 7.62 Results of all annotations with the linked weighted score model

As seen in the picture above, there are many numbers after a comma. The user can modify the weighted score model formula in the "Settings" view to show only 3 numbers.

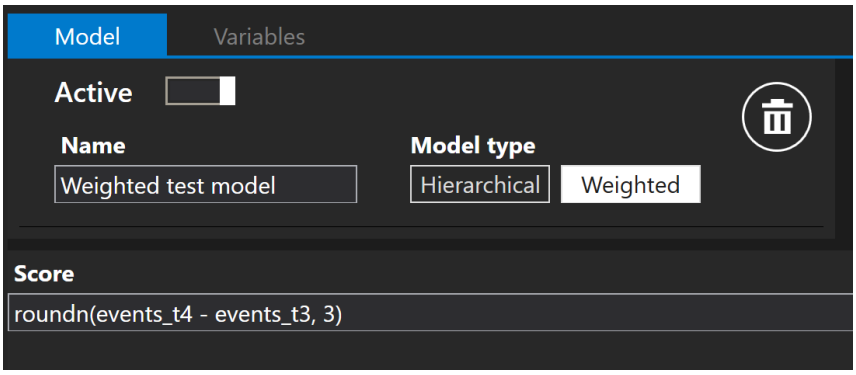


Figure 7.63 Modified weighted score model to show 3 numbers after the comma

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.

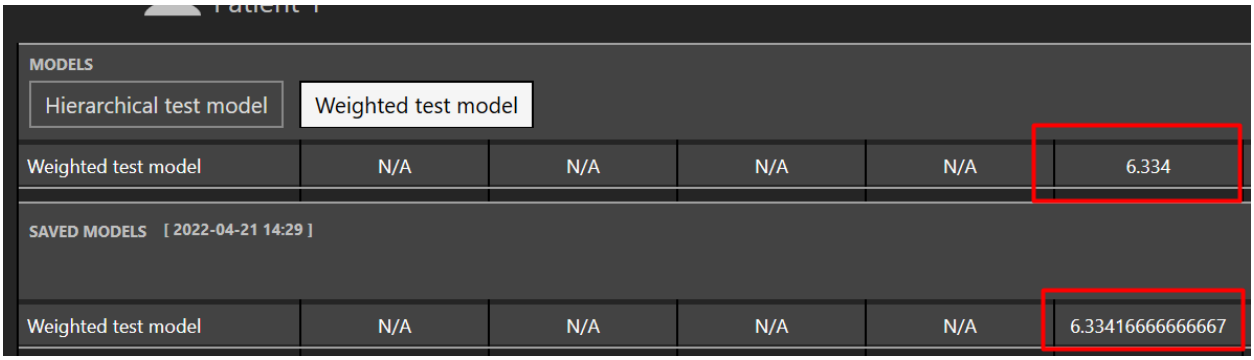


Figure 7.64 Results of all annotations with the linked weighted score model

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, it will list 3 options where selection between making the video, the image or the Report is possible. In this case, the user should press the “Video” button.

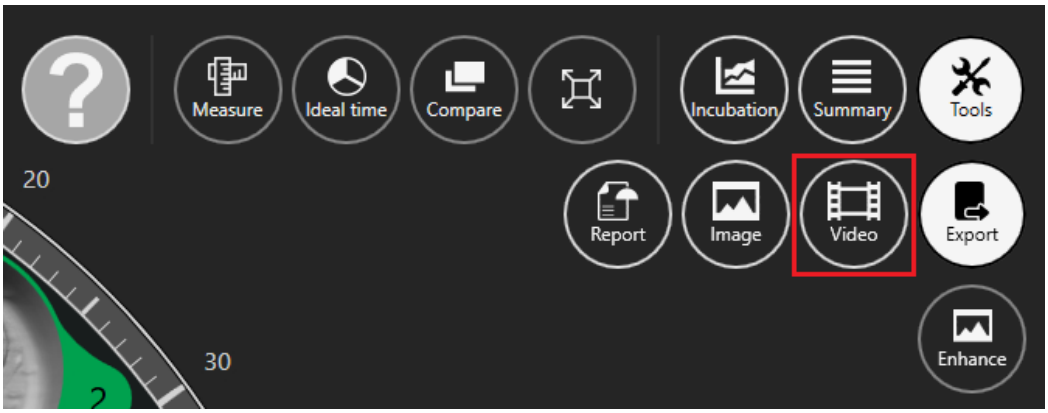


Figure 7.65 The "Export" option view

When the user selects the video option, the view changes to the video selection view.

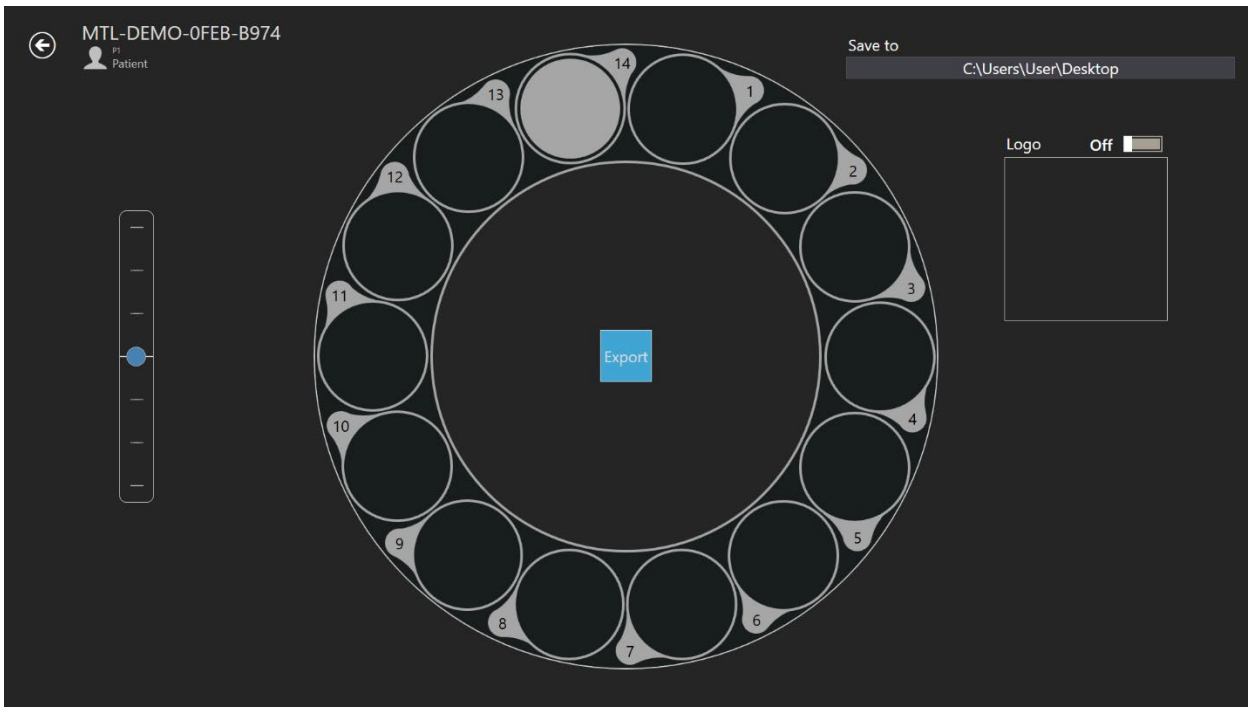


Figure 7.66 The video export view

The timelapse video that the user wants to export can be selected here by clicking the desired well number. In the picture above, only the 14th well is selected. 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.

The user can choose where to save the exported video. The resulting 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.

⚠ **The user should always wait for the video export to complete.**

How to export an image:

When pressing on the "Image" button, there is a possibility to export the selected image.

When clicking the "Export" button, it will list 3 options where selection between making the video, the image or the Report is possible. In this case, the user should press the "Image" button.

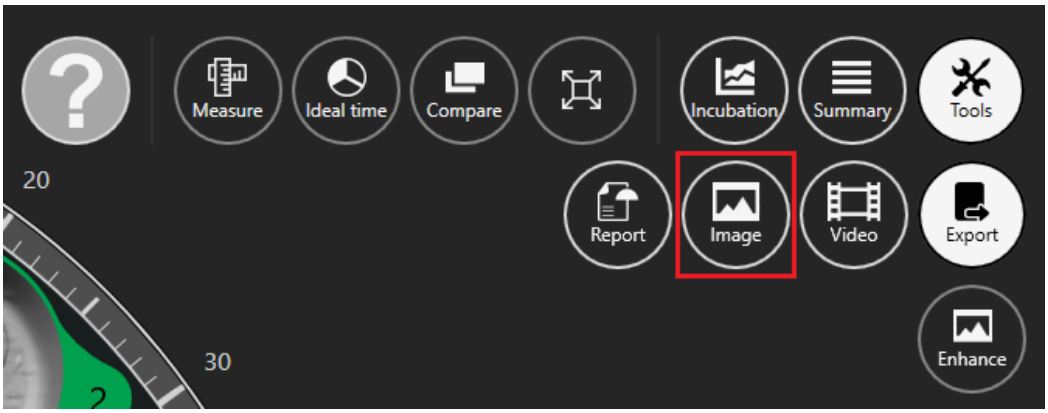


Figure 7.67 Selected image exportation button

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

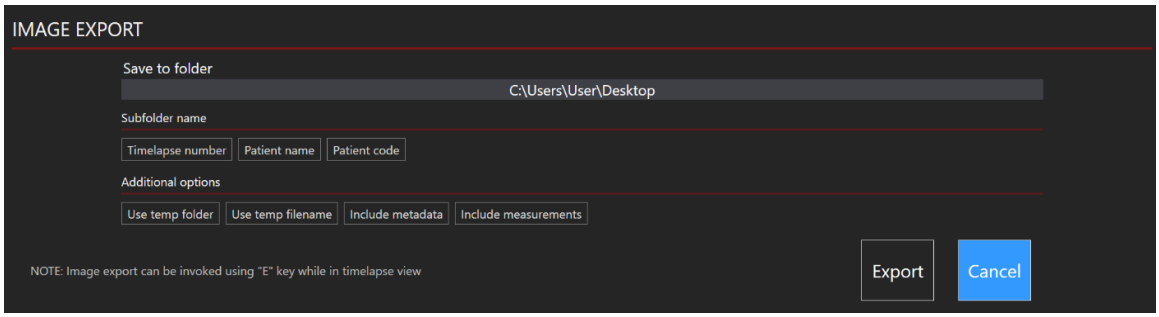


Figure 7.68 All options are inactive

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”.

By pressing on any of the options, they will be included in the exported file. They must be in white.

Image export can also be initiated using the “E” key on the keyboard.

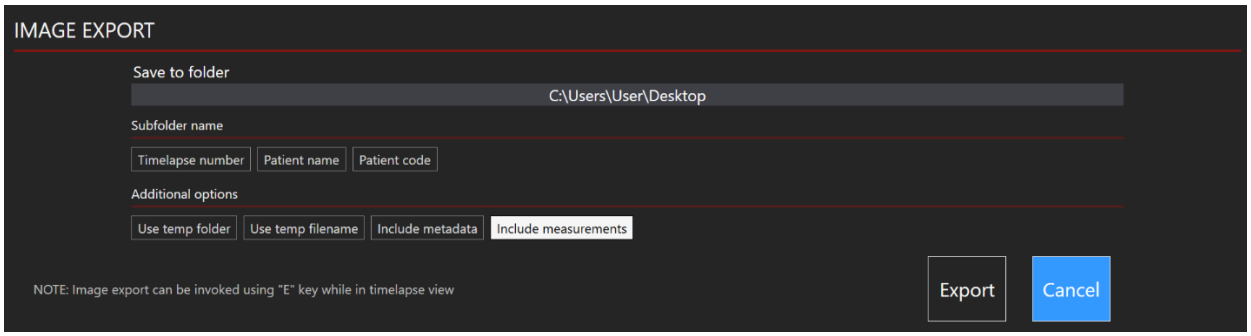


Figure 7.69 “Include measurements” option active

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!

How to export a report:

When clicking the “Export” button, it will list 3 options where selection between making the video, the image or the Report is possible. In this case, the user should press the “Report” button.

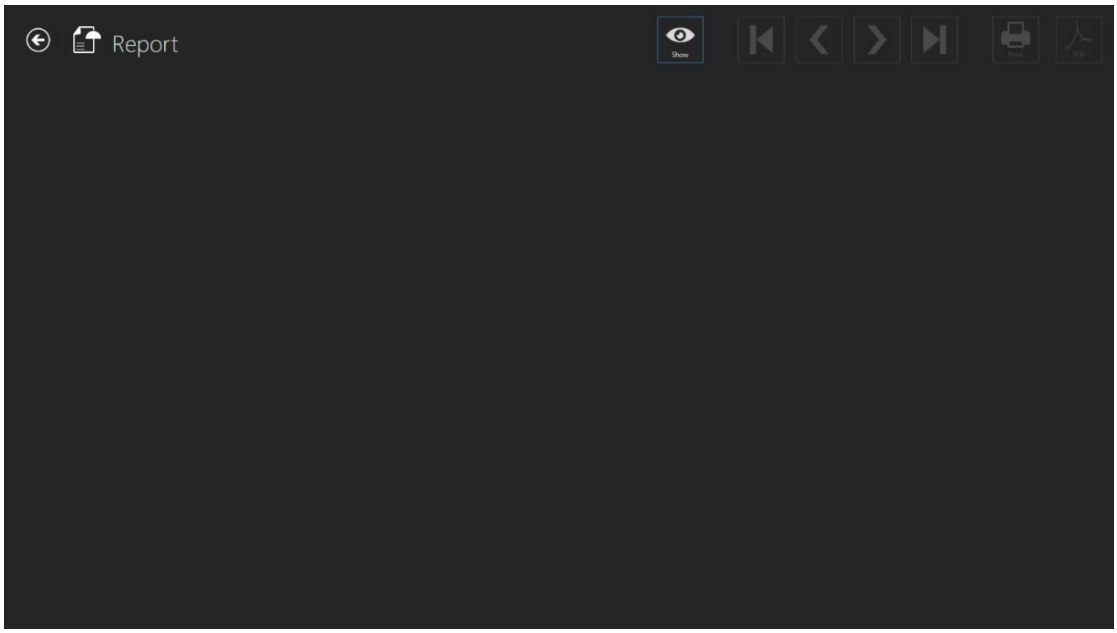


Figure 7.70 "Report" view

The Report can be shown on the screen by clicking the "Show" button. Near the "Show" button, navigation buttons can be used for moving between exported report pages. By clicking the 1st or 4th button, the user can navigate to the first and the last report page. By clicking the 2nd and 3rd button, the user can navigate one page per click. The user can select to print or make a PDF file.

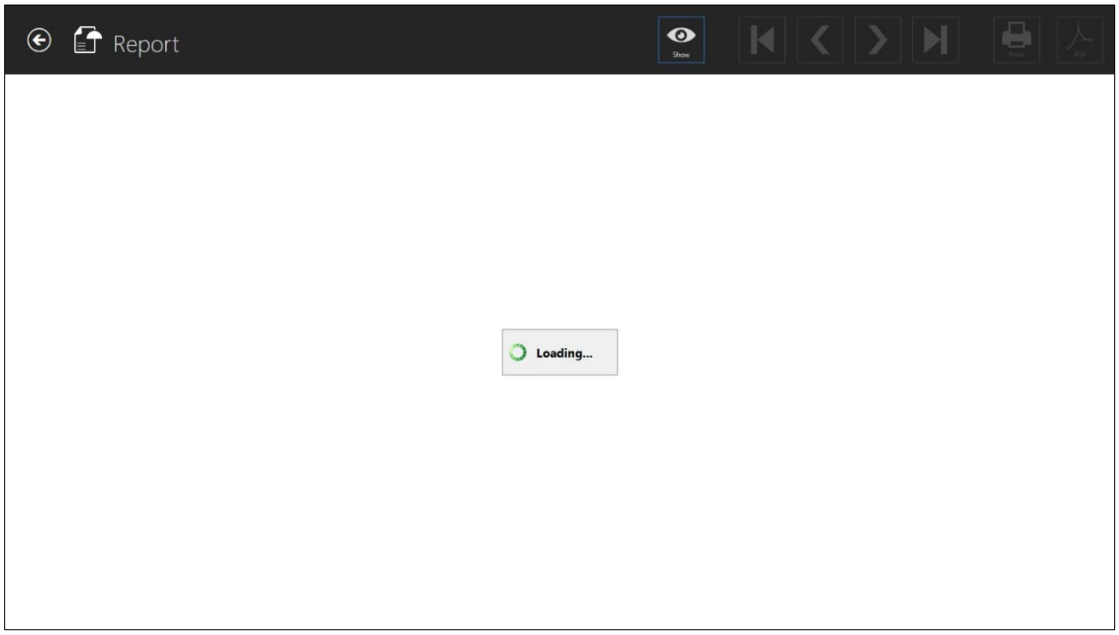


Figure 7.71 Report loading view

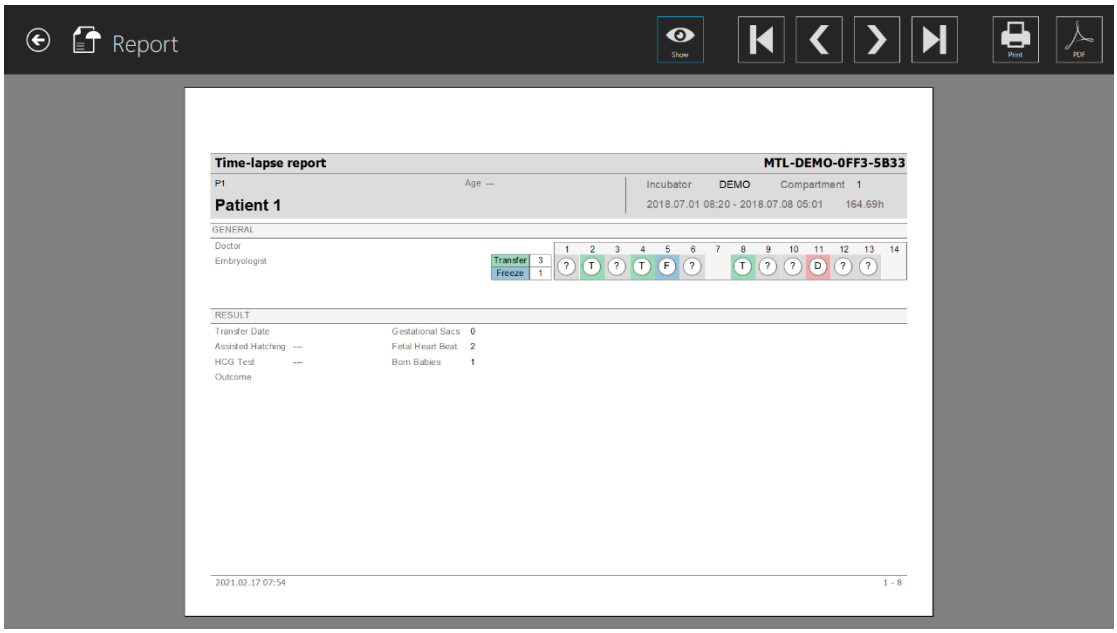


Figure 7.72 Timelapse report view (general page)

⚠ **The Report may take a while to load.**

In the picture below there are all development images which were included when events were annotated. When the timelapse Report is generated, images with measurements will be included automatically.

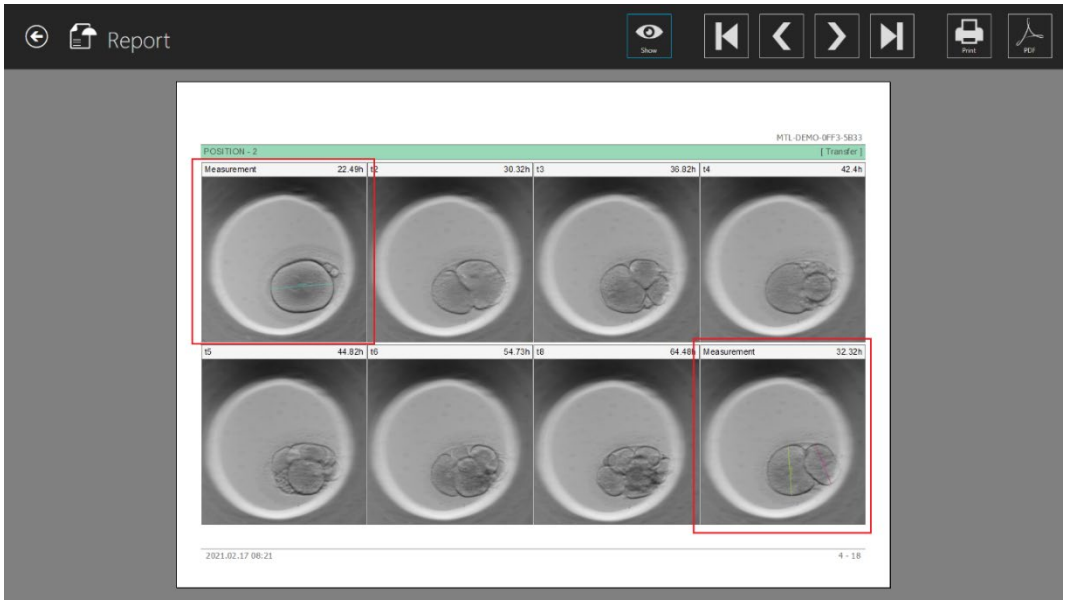


Figure 7.73 Images with measurement in a generated timelapse report

In the picture below there are all annotation overview matrices.

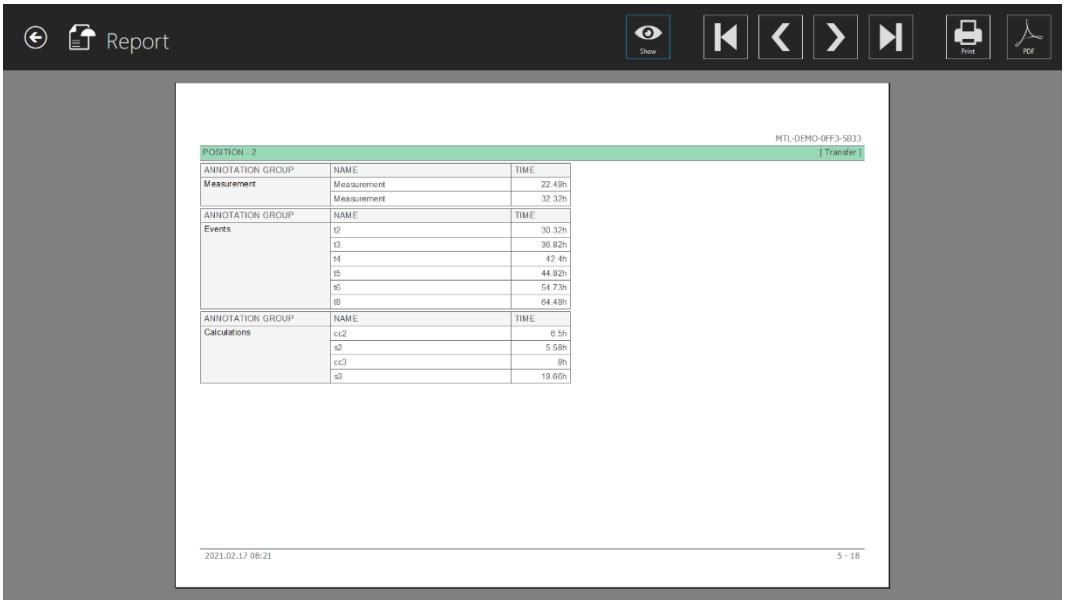


Figure 7.74 Timelapse report view (annotations)

All new additional information (i.e., outcomes, gestational sacs, etc.) is also included in the timelapse Report (Figure 7.74).

7.3.2.10 Image presets

On the upper right corner of the main MIRI® TL family's multiroom IVF incubators screen, there is a new "Tools" button.

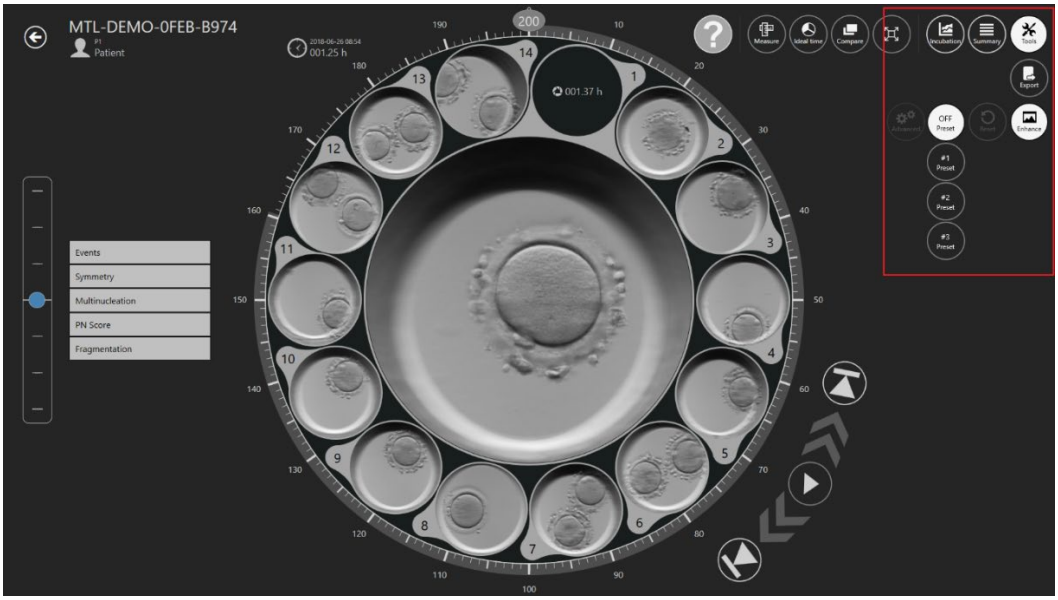


Figure 7.75 "Tools" button in the main MIRI® TL family's multiroom IVF incubators screen

After pressing the “Tools” button, it will list two options: “Export” and “Enhance”.

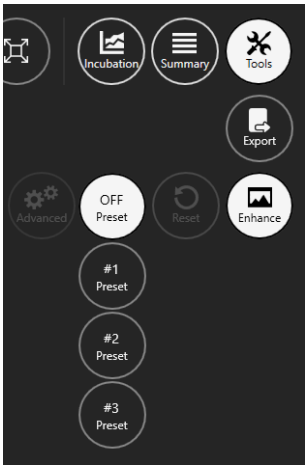


Figure 7.76 Image enhancement tool

As a default, image enhancement tool will list 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.

Figure 7.77 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.

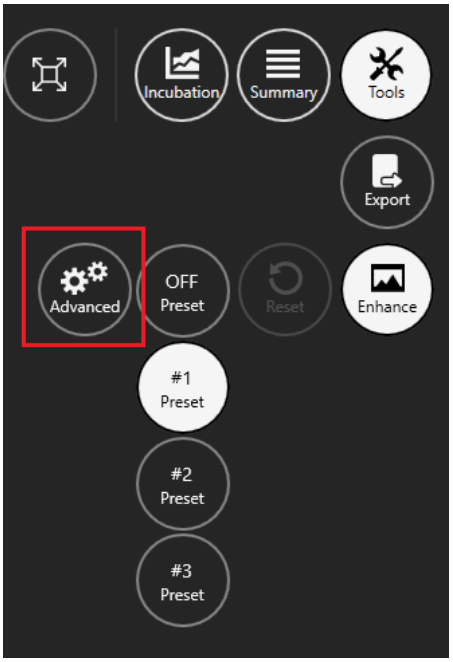


Figure 7.78 Advanced image enhancement settings

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

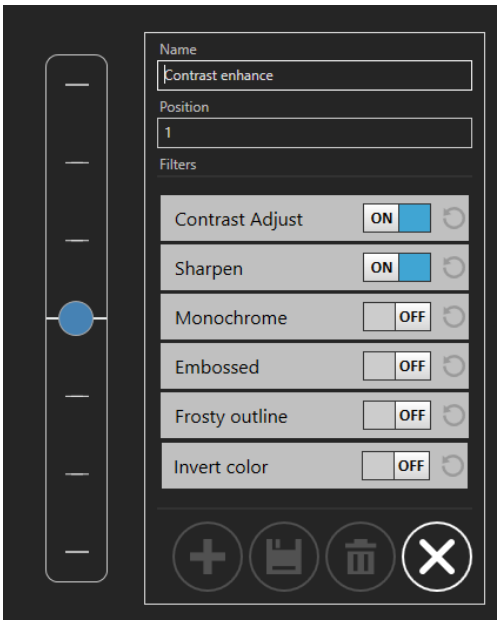


Figure 7.79 #1 Preset advanced settings

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.

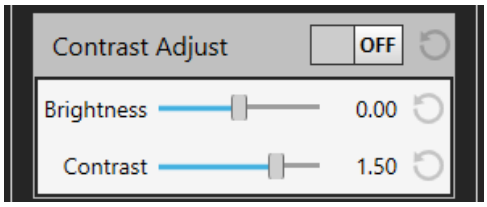


Figure 7.80 Contrast adjustment settings

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.

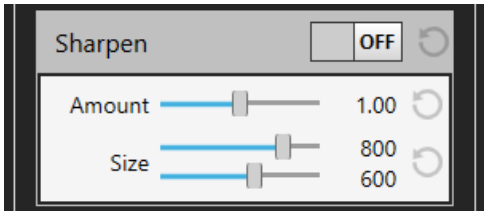


Figure 7.81 Sharpen settings

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.

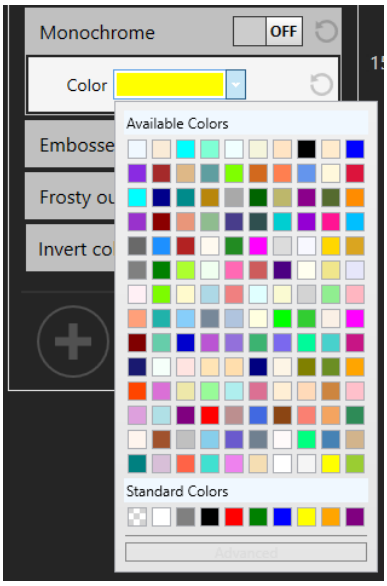


Figure 7.82 Standard color settings

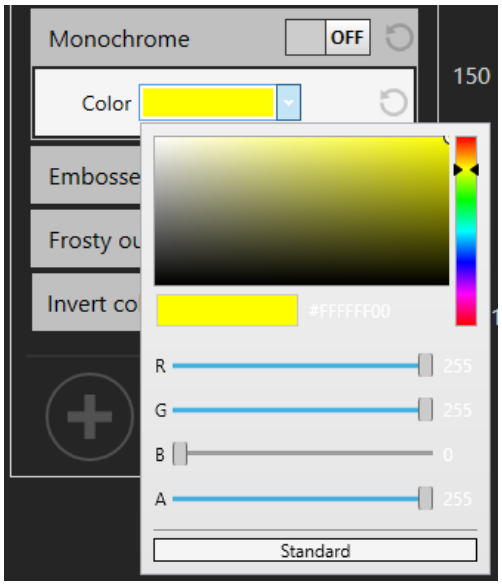


Figure 7.83 Advanced color settings

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.

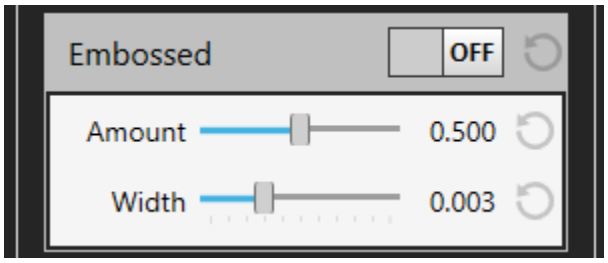


Figure 7.84 Embossed settings

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.

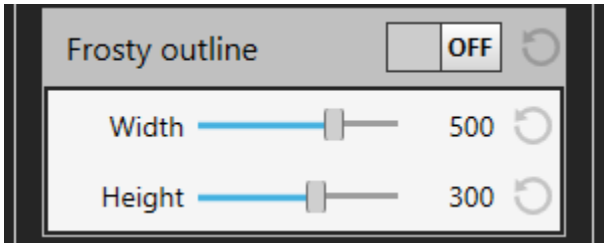


Figure 7.85 Frosty outline settings

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

Figure 7.86 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.

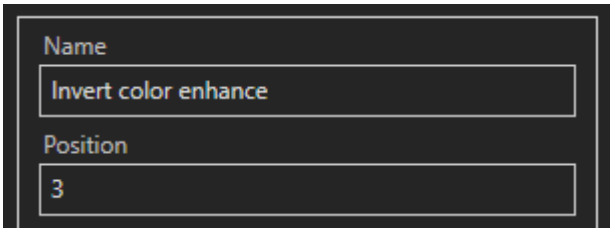


Figure 7.87 Creation of a new image preset name and position

When the user creates the image preset for the first time, the "Position" should be left at number 3 since after pressing "Add new preset" it will automatically set to number 4.

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

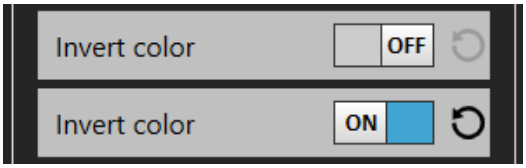


Figure 7.88 "ON/OFF" button

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

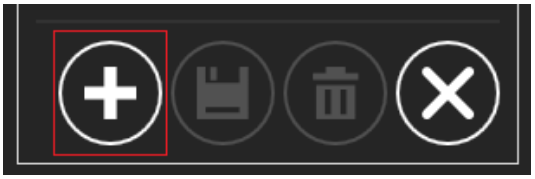


Figure 7.89 "Add new preset" button

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

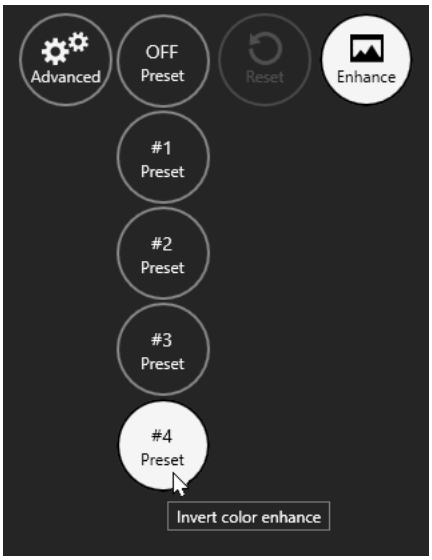


Figure 7.90 Created image preset name

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.

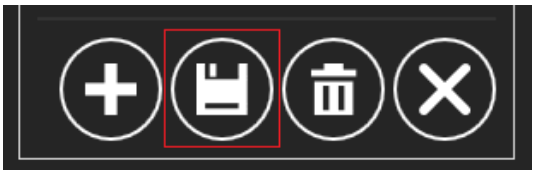


Figure 7.91 "Save changes" button

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 7.89.

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

Figure 7.92 "Delete preset" button

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

Figure 7.93 "Cancel" button

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

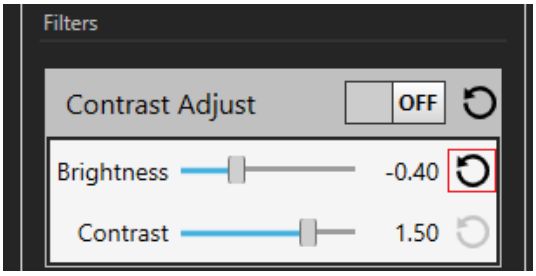


Figure 7.94 Reset the modified image enhancement settings button

The "Reset" button is also near the "Enhance" button.

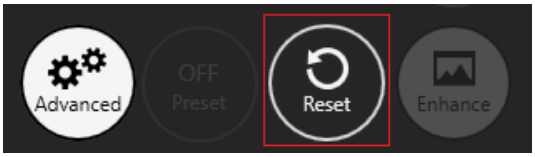


Figure 7.95 "Reset" button

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

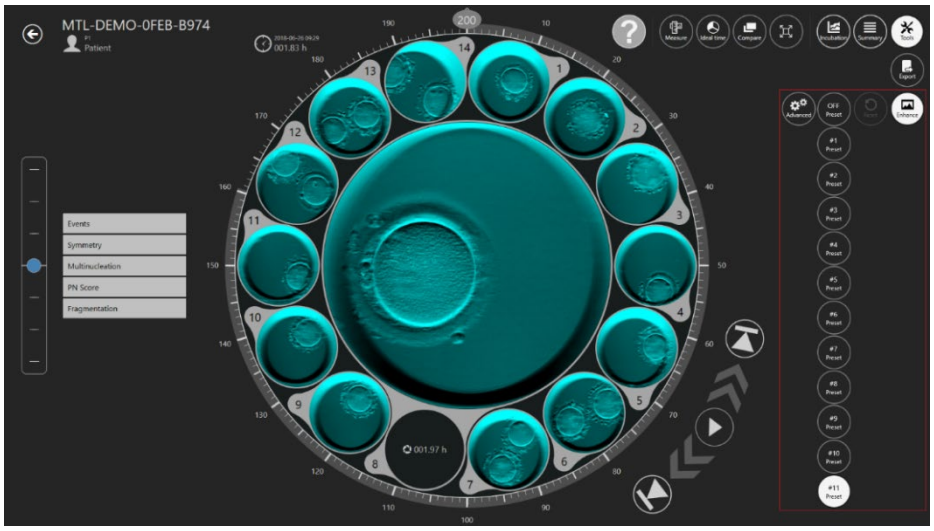


Figure 7.96 Maximum number of image presets

7.4 Patients

7.4.1 Patient list view

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

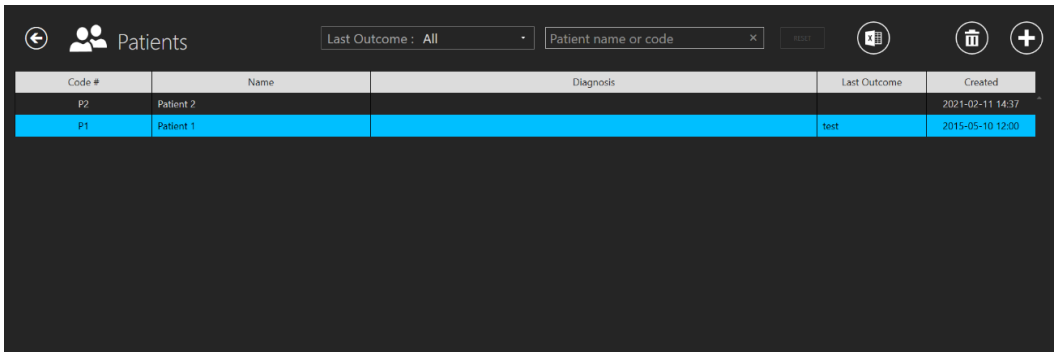


Figure 7.97 Patient list view

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.

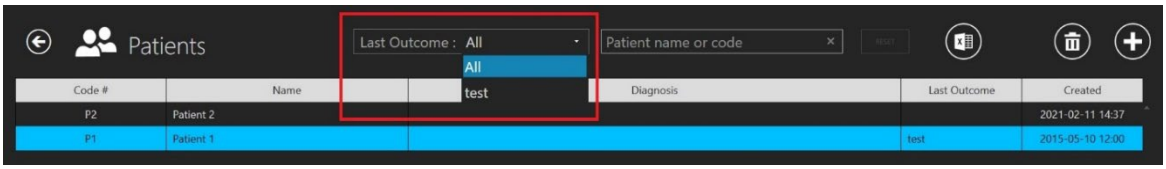


Figure 7.98 Last outcome filtration

There is also a newly added “Last outcome” column in the patient treatment list. It is shown in the picture below.

Figure 7.99 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.

By pressing on a “Report” button in the top right corner of the patient’s list view, the user can generate a patient's annotation file.

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

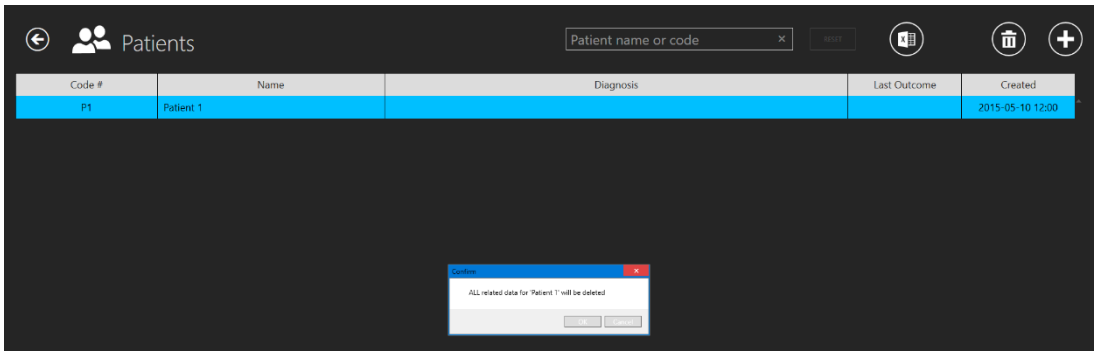


Figure 7.100 Confirmation window that all selected patient’s data will be deleted

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

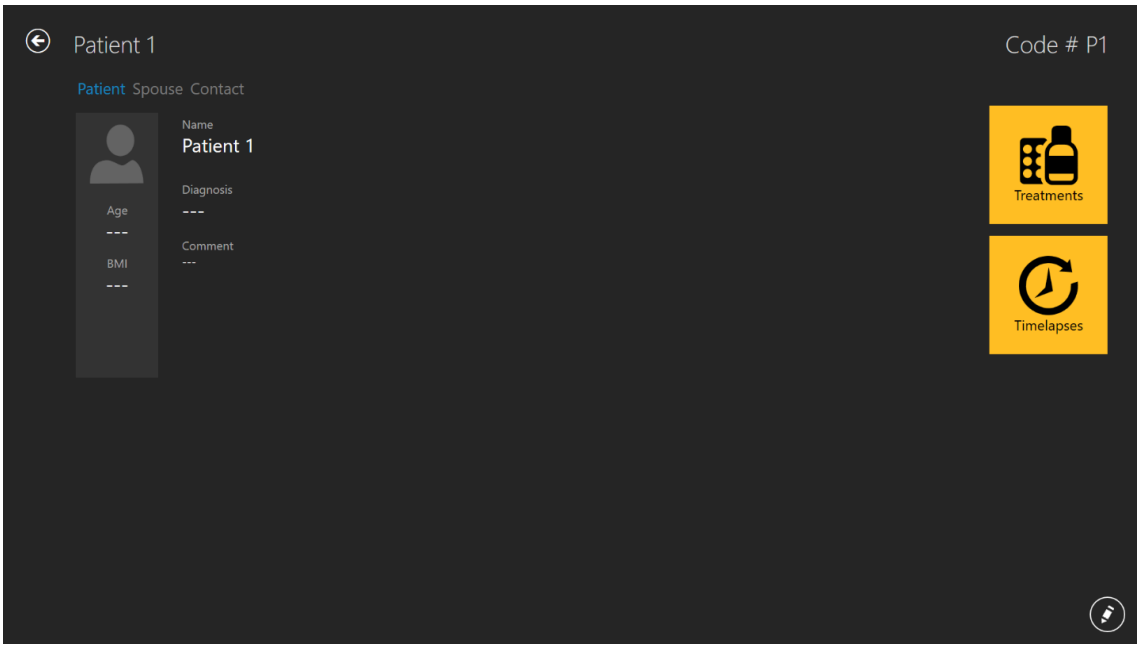
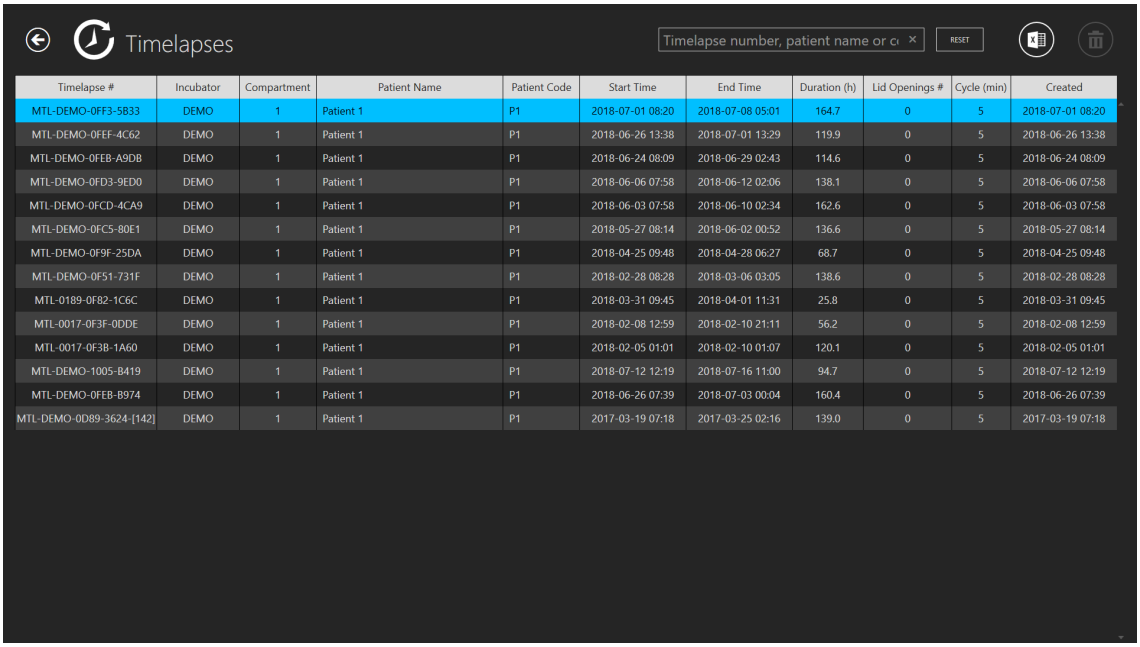


Figure 7.101 Selected patient view

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



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-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-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-0189-0F82-1C6C	DEMO	1	Patient 1	P1	2018-03-31 09:45	2018-04-01 11:31	25.8	0	5	2018-03-31 09:45
MTL-0017-0F3F-0DDE	DEMO	1	Patient 1	P1	2018-02-08 12:59	2018-02-10 21:11	56.2	0	5	2018-02-08 12:59
MTL-0017-0F3B-1A60	DEMO	1	Patient 1	P1	2018-02-05 01:01	2018-02-10 01:07	120.1	0	5	2018-02-05 01:01
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 7.102 Selected patient timelapses view

7.4.2 Patient view

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

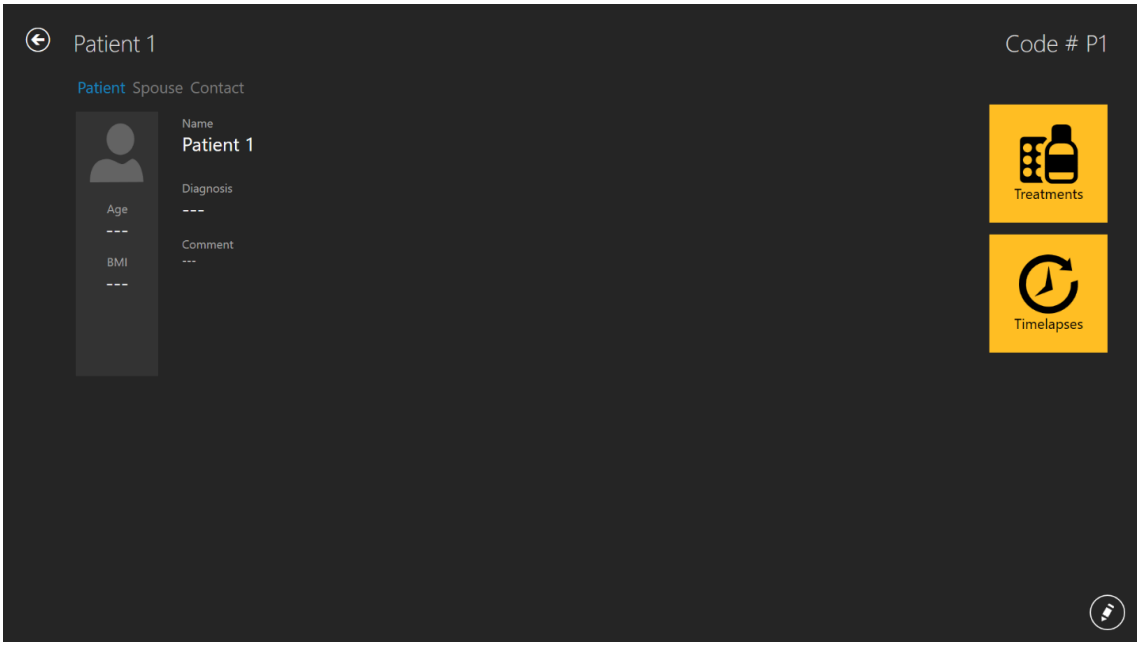


Figure 7.103 Selected patient view

At the right bottom of the screen, there is an “Edit” button.

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 in the patient list view lets the user add a new patient. When it is pressed, a new view opens up:

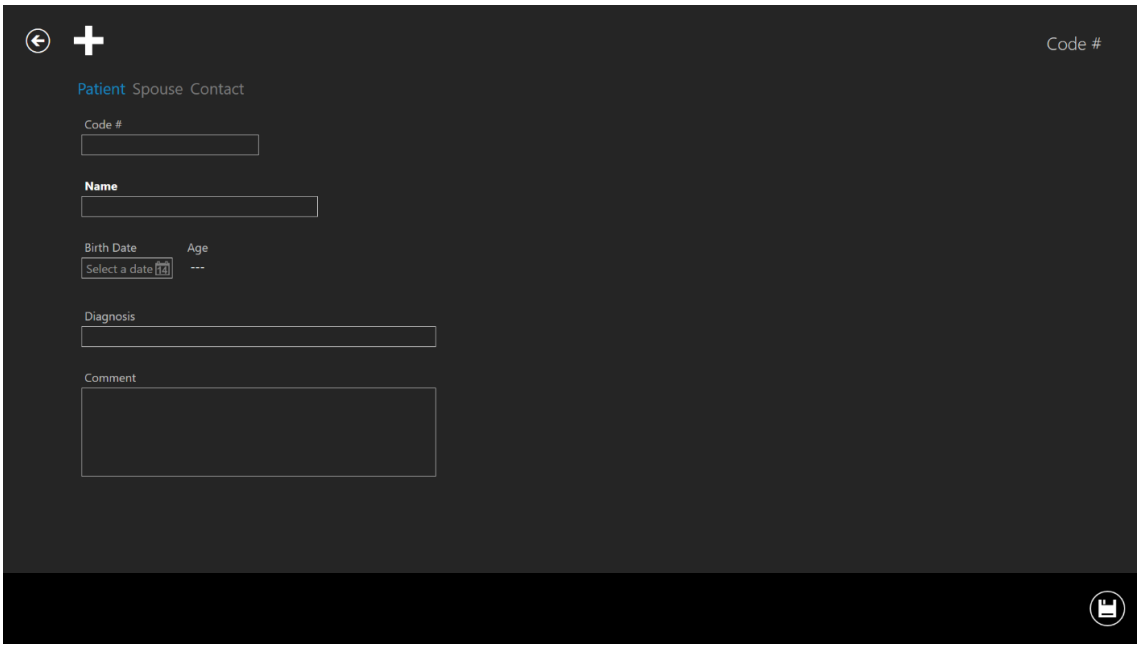


Figure 7.104 New patient creation window

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.

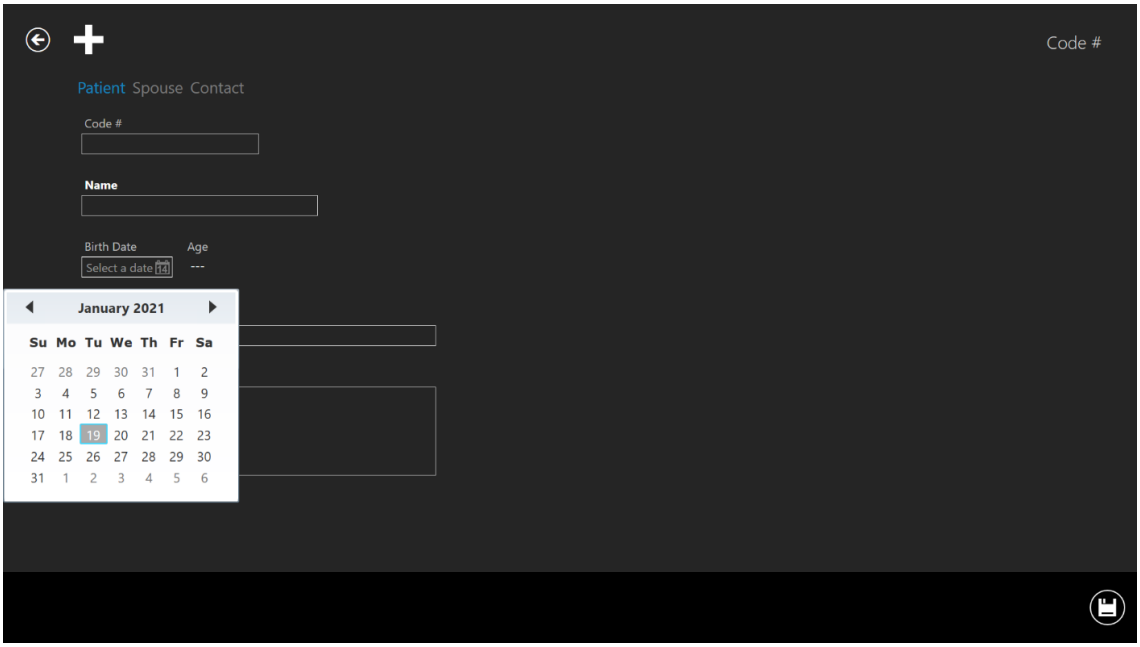


Figure 7.105 Birthdate input

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.

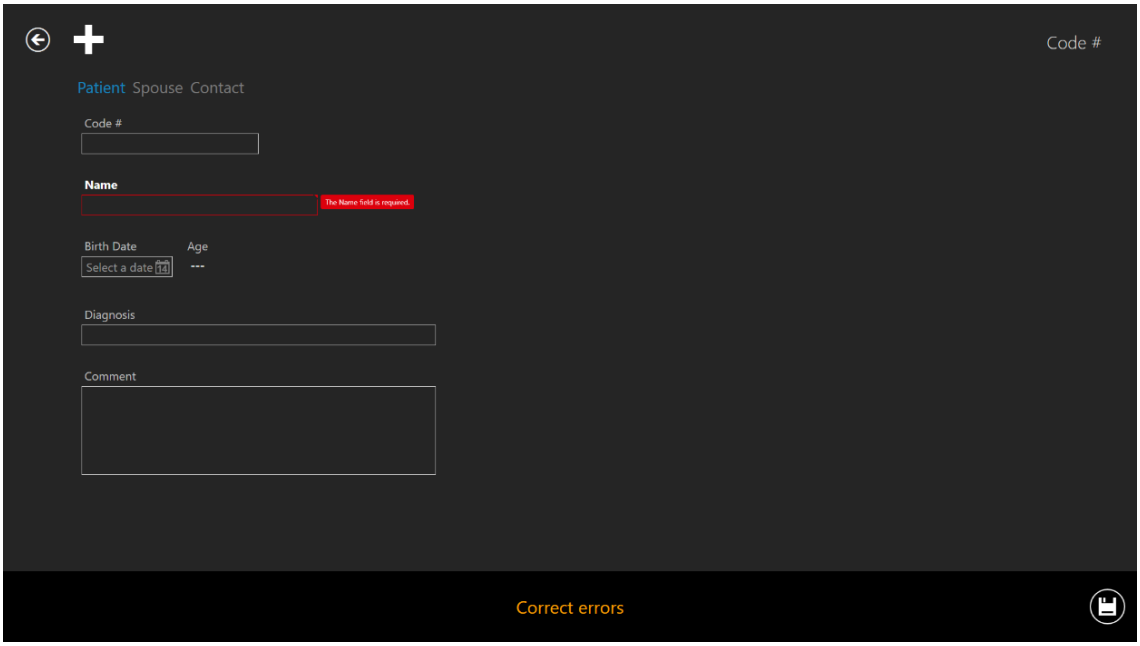


Figure 7.106 Warning information

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.

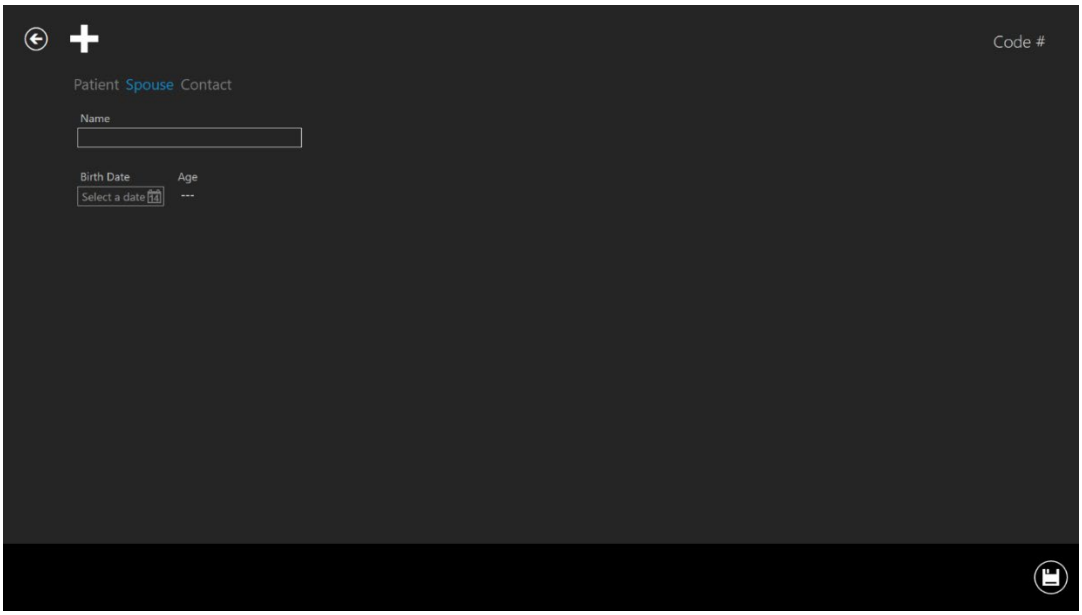


Figure 7.107 Information about spouse window

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.

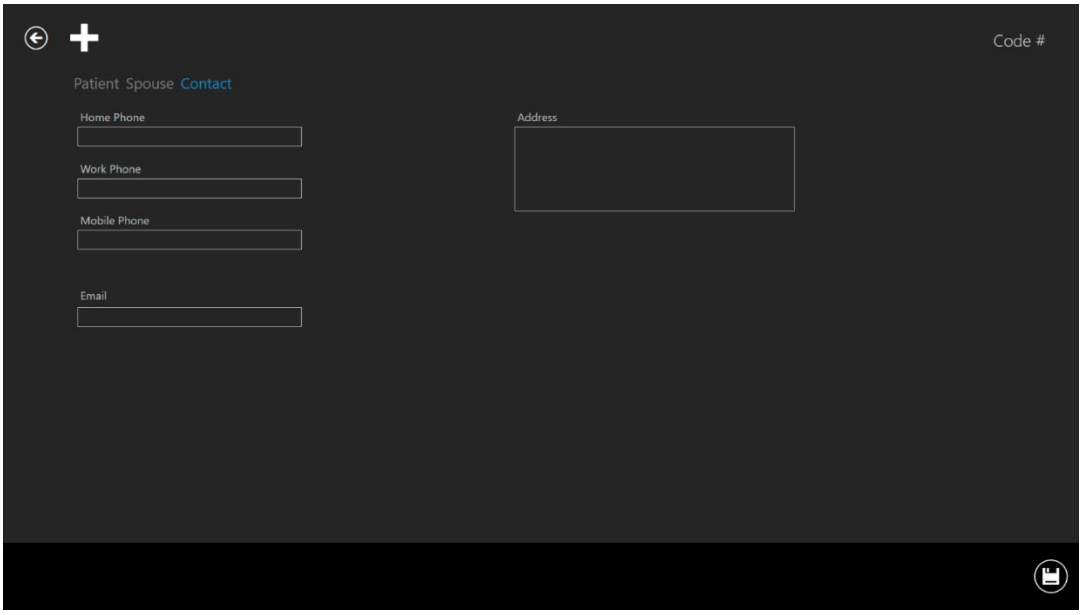


Figure 7.108 Contact information window

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 provide 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.

Figure 7.109 Selected patient treatment view

Pressing the "Plus" button opens up the new treatment window.

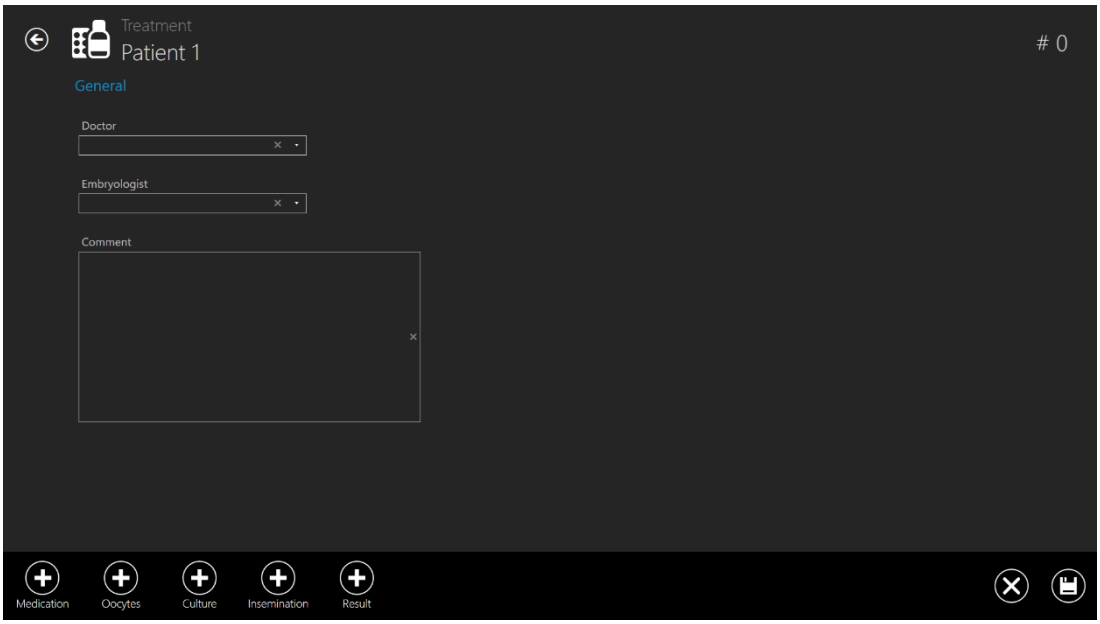


Figure 7.110 New treatment window

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.

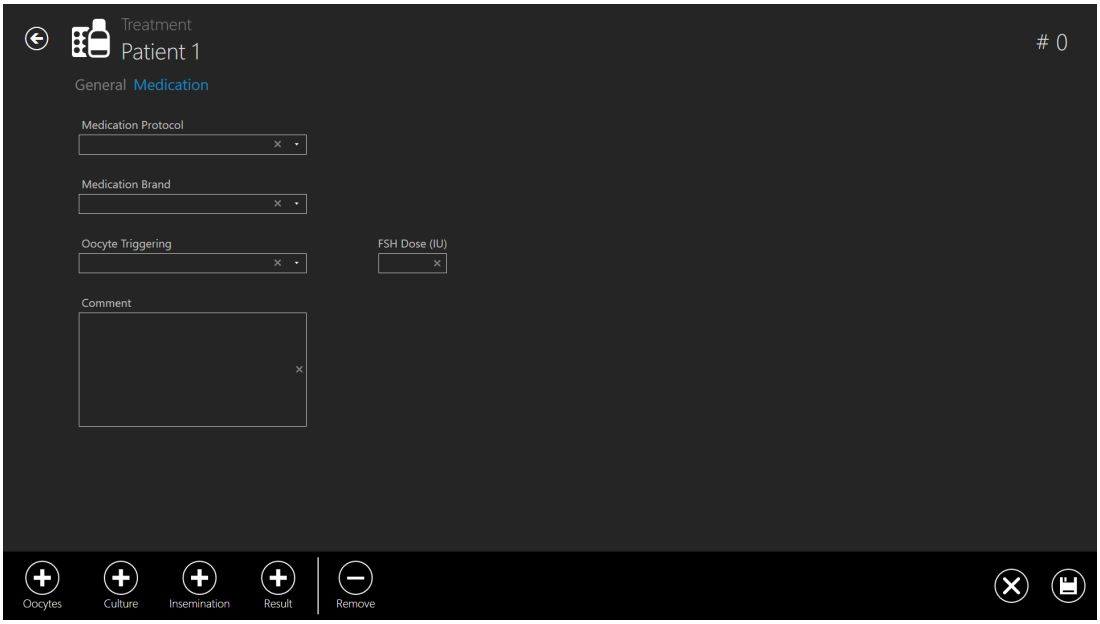


Figure 7.111 Added “Medication” section

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.

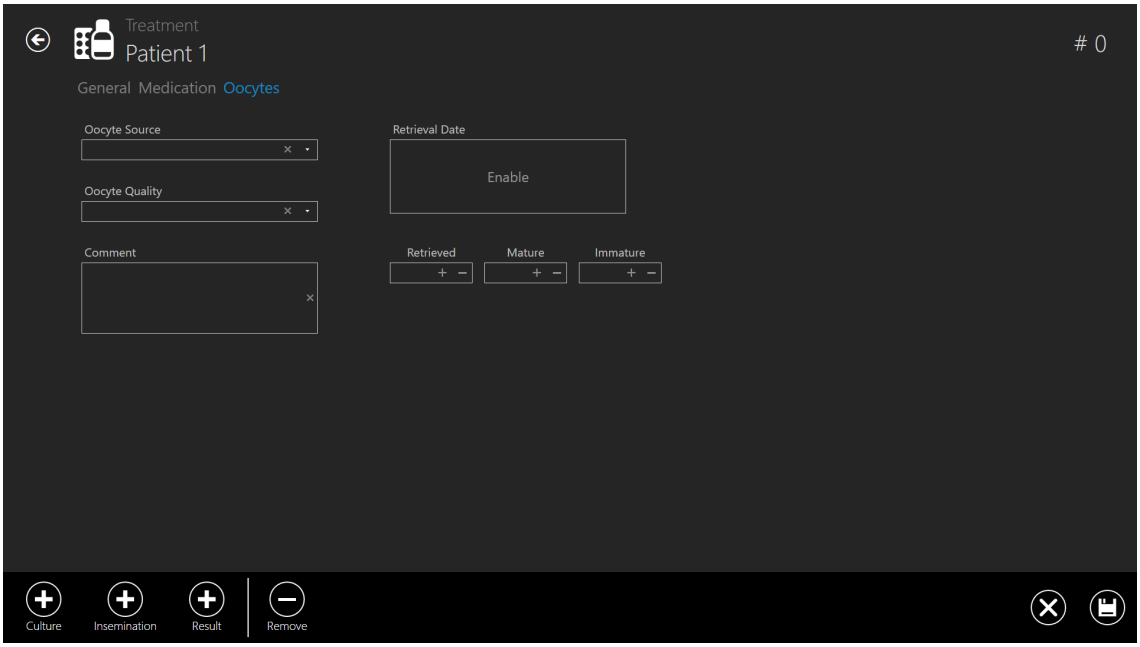


Figure 7.112 Added "Oocytes" section

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.

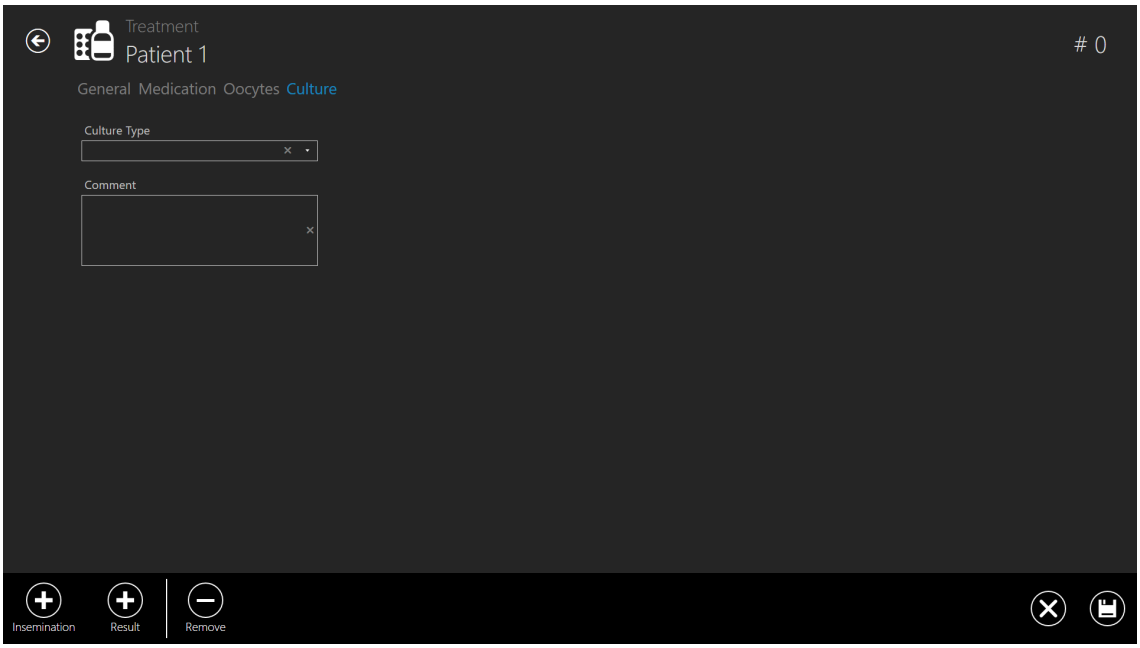


Figure 7.113 Added "Culture" section

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.

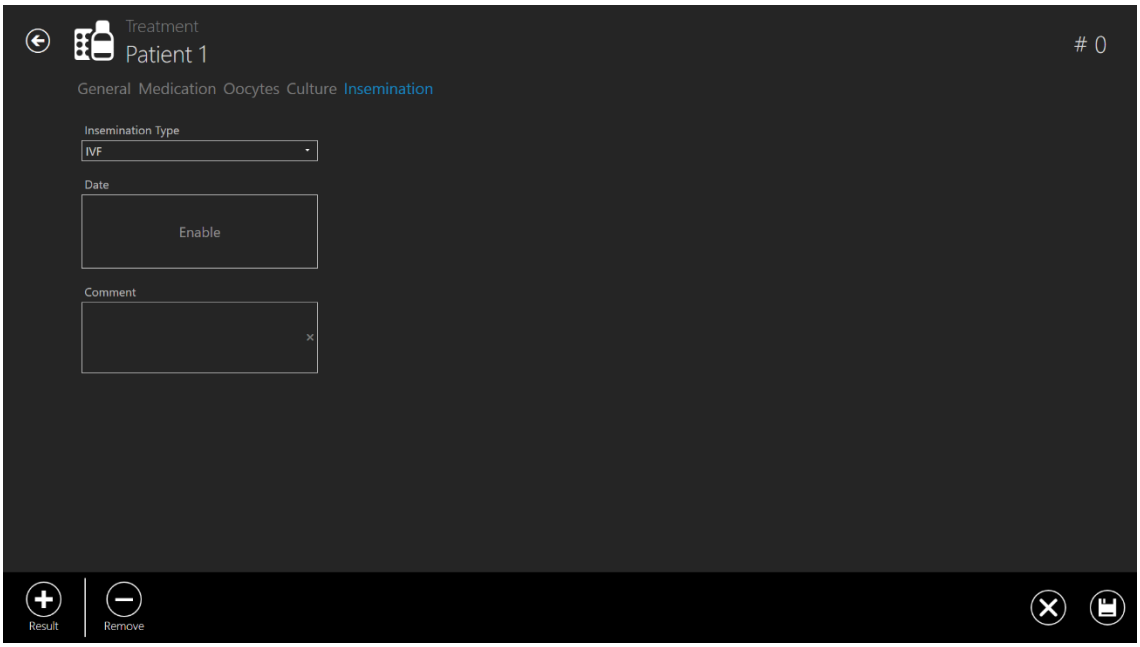


Figure 7.114 Added “Insemination” section

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.

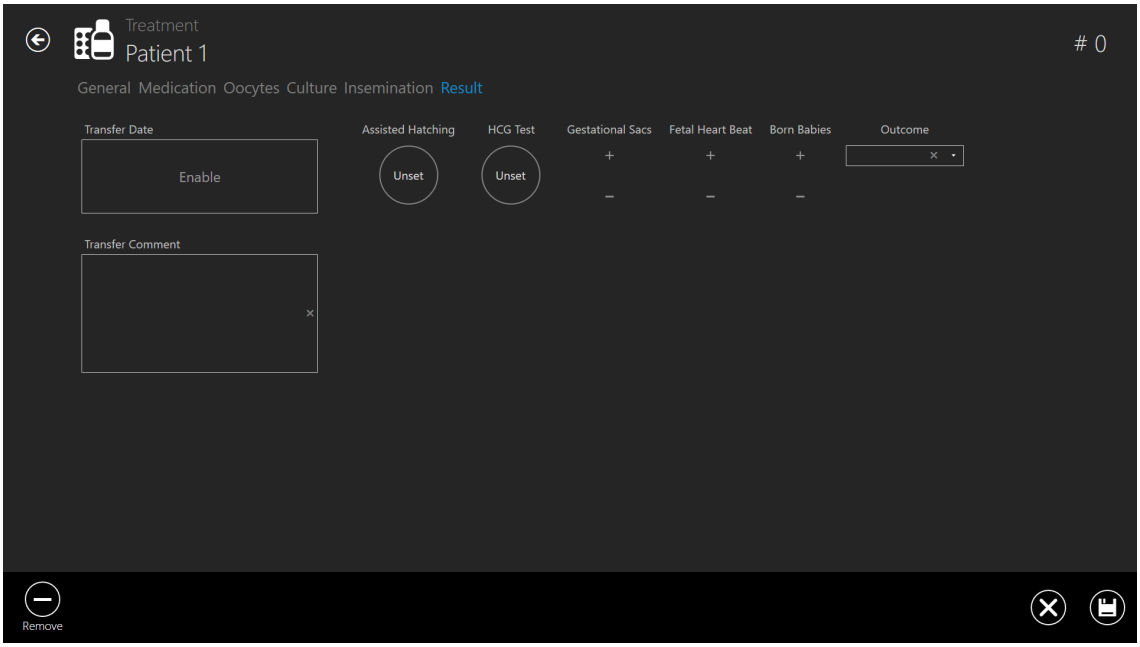


Figure 7.115 Added “Result” section

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. For example, “Outcome”, “Patient name or code”, “Transfer comment”, etc.

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

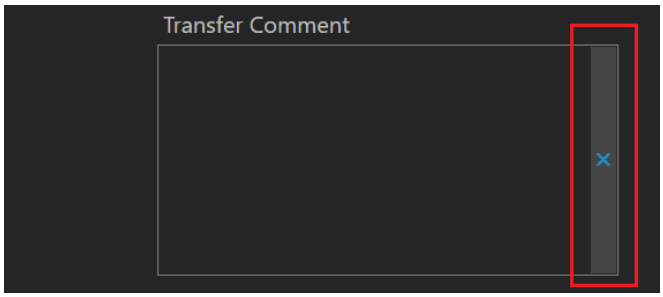


Figure 7.116 "Clear" button

7.4.4 Timelapse creation view

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

Figure 7.117 "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, there will not be visible in the "Select incubator" window below.

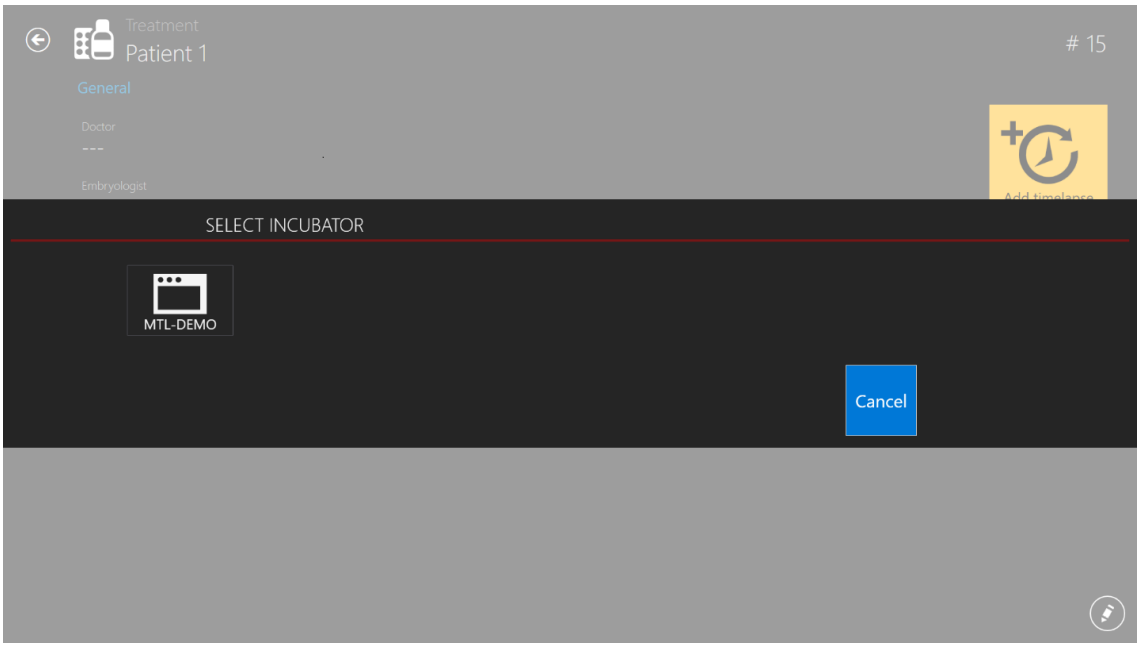


Figure 7.118 Select the device in which timelapse is sent

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 enabling and disabling the incubator, please refer to the "7.5 Incubators" 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 7.119 Treatment view when the timelapse has been made

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

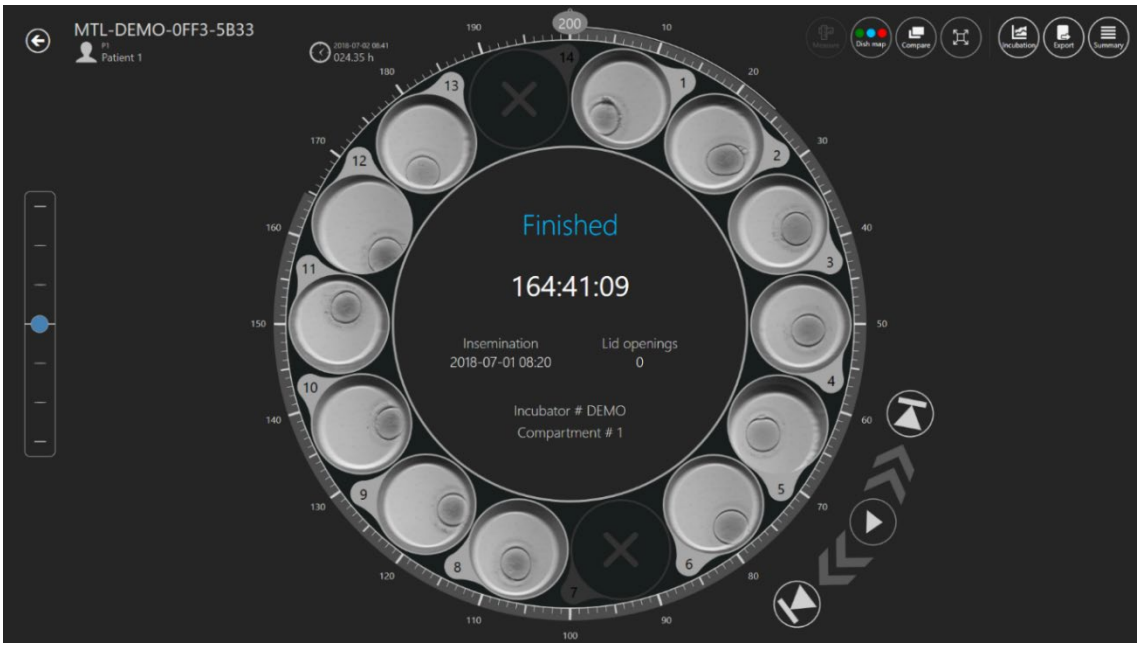


Figure 7.120 The timelapse view of a specific patient

7.5 Incubators

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 7.121 “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 7.122 “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 4th chamber temperature incubation data is shown.

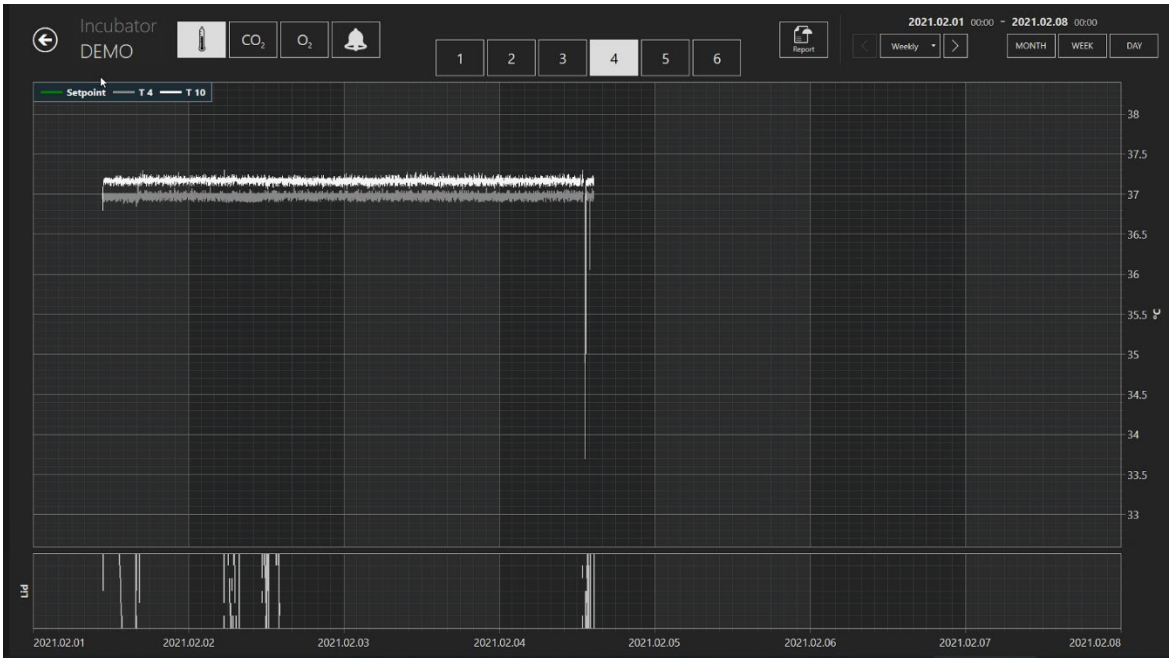


Figure 7.123 "DEMO" incubator temperature incubation data log view

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.

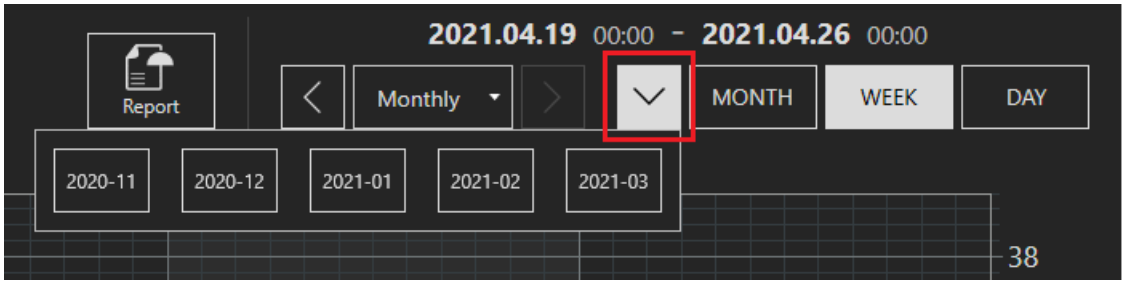


Figure 7.124 Incubation data selection options

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.

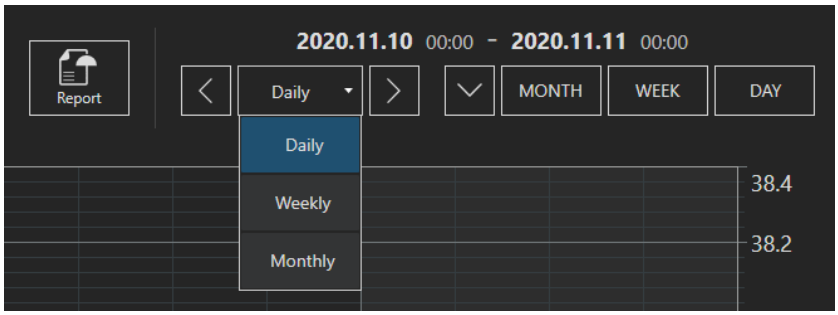


Figure 7.125 Incubation data selection options

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

7.6 Settings

In this section, the user can set the events, the results, the ideal times and create new embryo states. It has a default value when the device is delivered but must be adapted to unique user's preferences and needs.

By pressing the "Settings" button, it opens up the settings view, which contains "Annotations" and "Embryo States" sections.

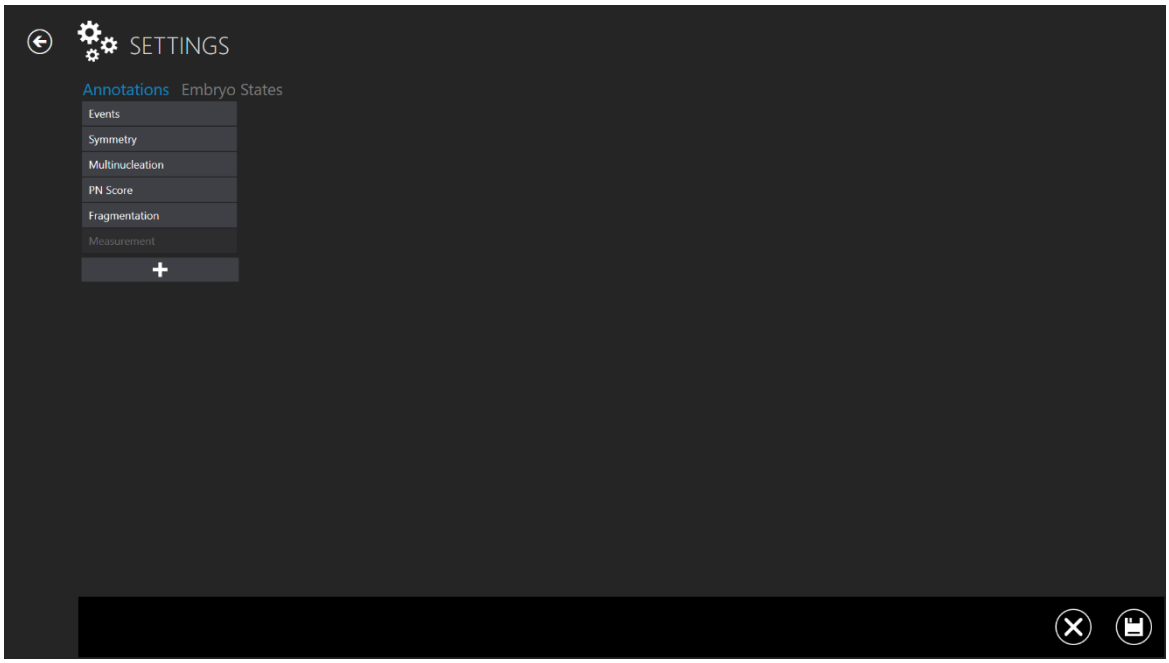


Figure 7.126 Settings view

It shows the groups of annotations. A group can be added by pressing the "+" button that is the lowest among the groupings. A group can be removed by pressings the delete icon on the lower right side of the display.

7.6.1 Annotations

By pressing on the "Event" bar, it will open an event annotation view.

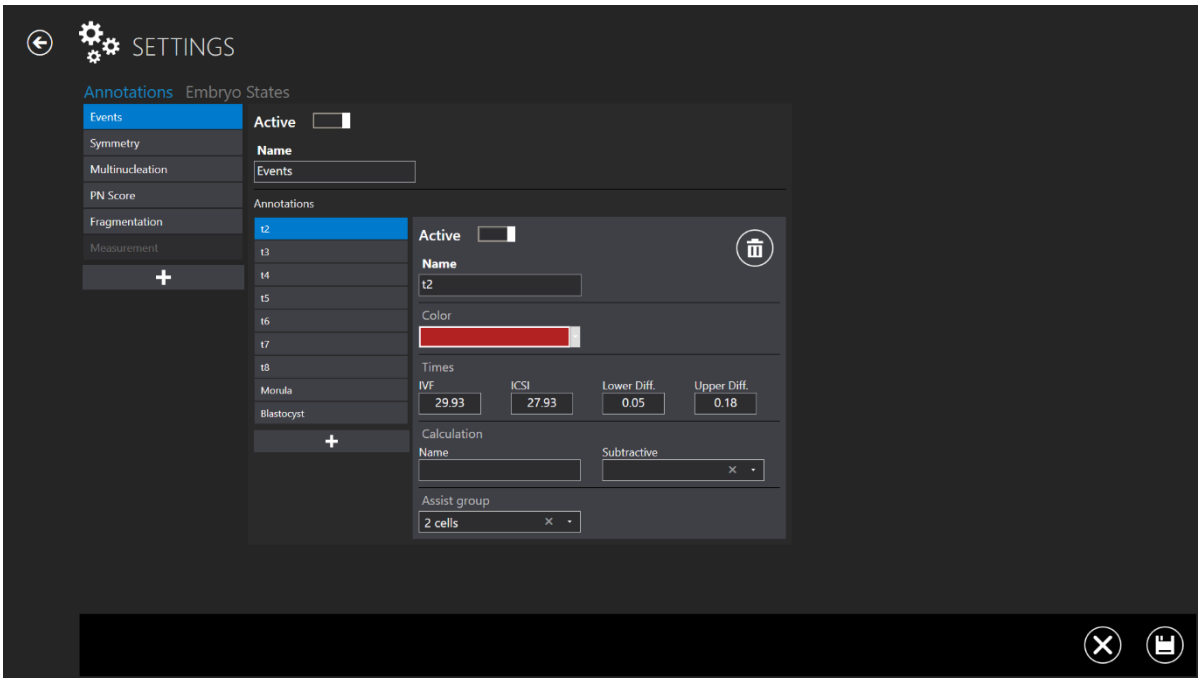


Figure 7.127 Settings – annotations – events view

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.

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.

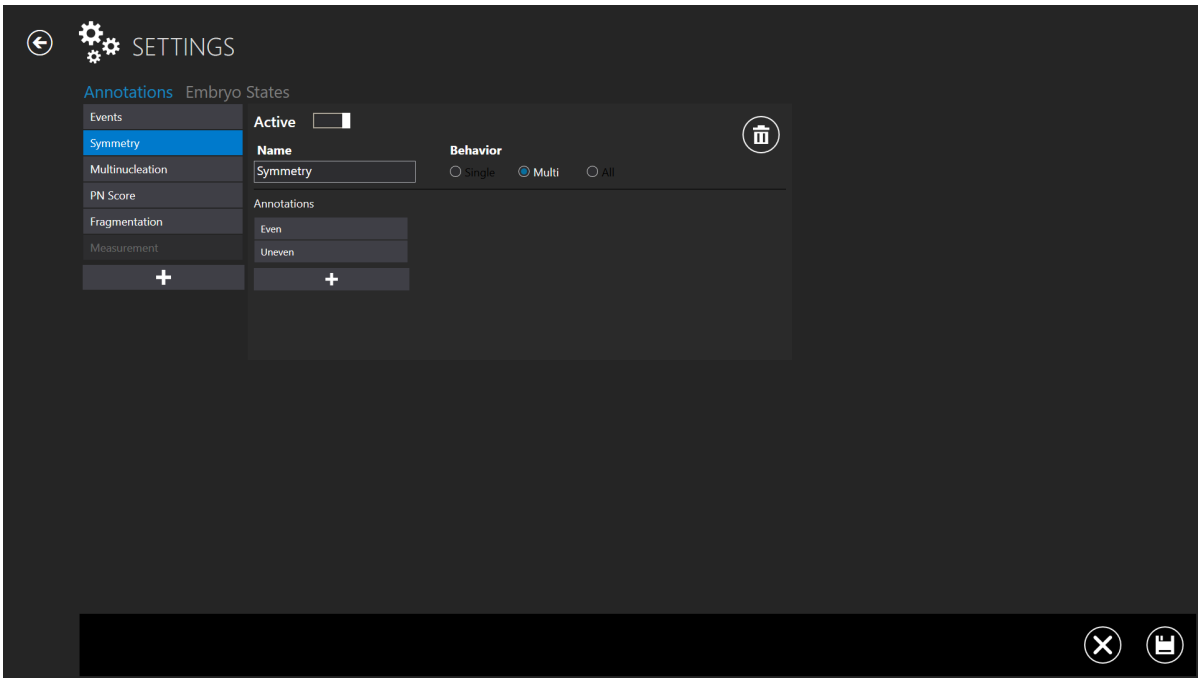


Figure 7.128 Settings – annotations – symmetry view

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 have a group of annotations linked, so the rest of the group goes away if that is chosen. This behavior is called “All”.

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

7.6.2 Embryo states

In previous versions, there was no other choice between settings, just the „Annotations“ section. With the 1.19.0.0 MIRI® TL family`s multiroom IVF incubators Viewer version, a newly added “Embryo States” section allows the user to add additional embryo states.

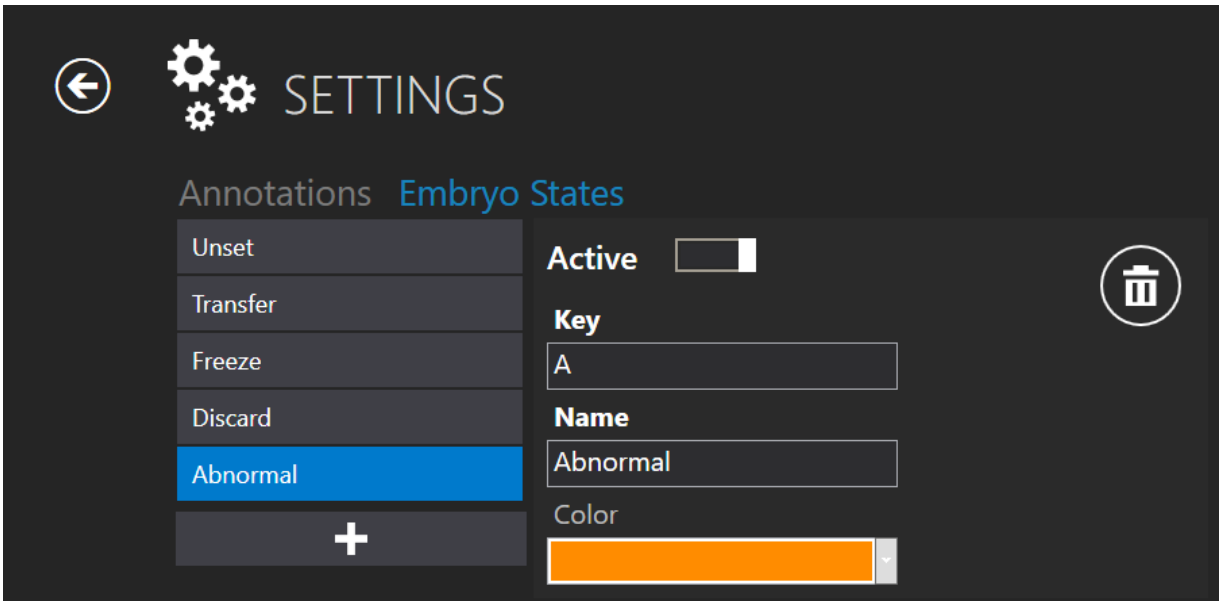


Figure 7.129 Active new embryo state

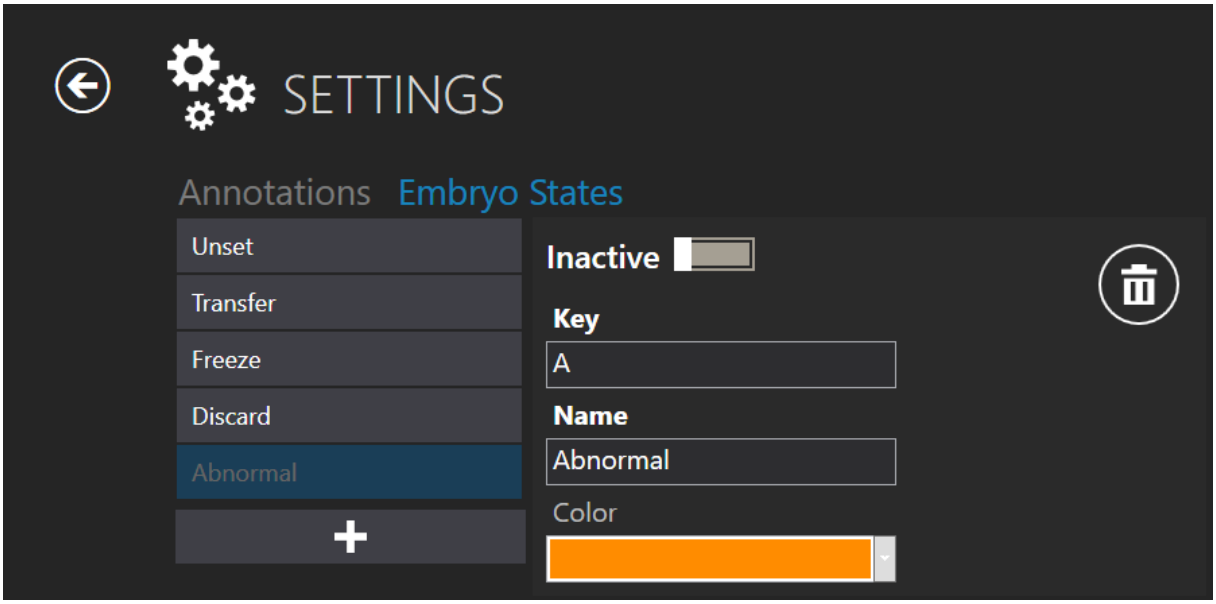


Figure 7.130 Inactive "Abnormal" embryo state

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.

7.6.3 Score models

With the 1.20.0.0 MIRI® TL family`s multiroom IVF incubators Viewer version, embryo score models can be created.

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

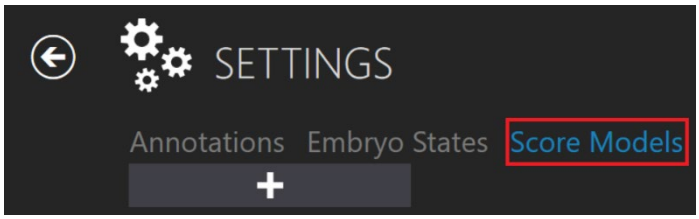


Figure 7.131 Score models

A score model input will be displayed by pressing the “+” button, where the user can create a desired embryo score model.

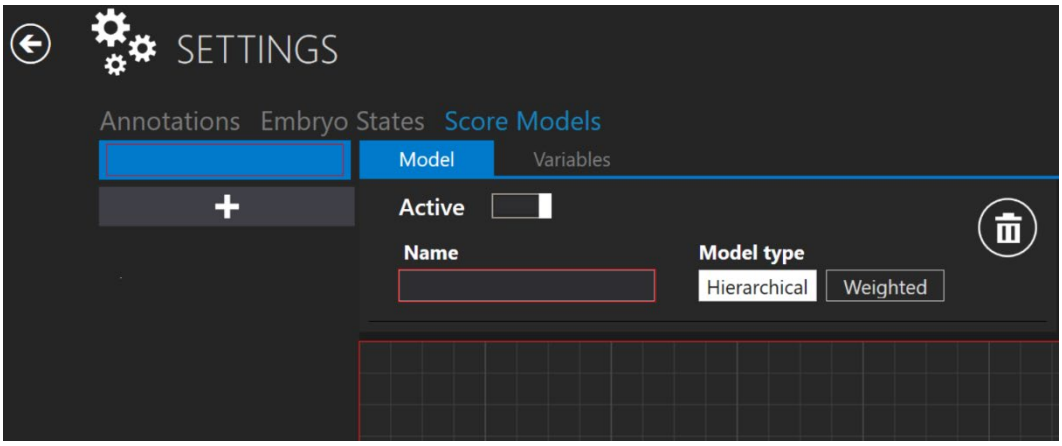


Figure 7.132 A new embryo score model creation window

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 by a formula.

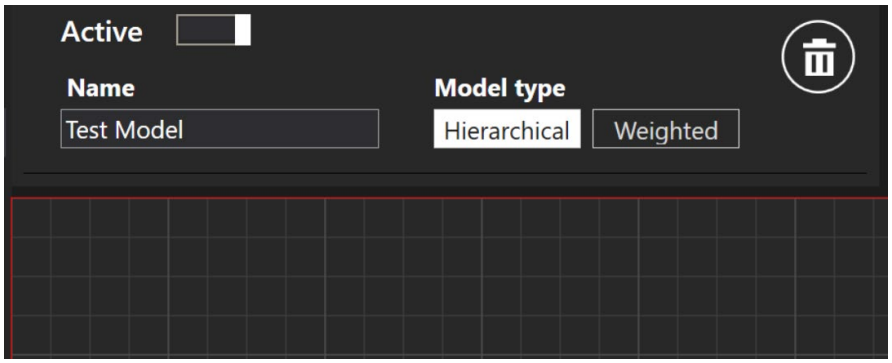


Figure 7.133 "Hierarchical" model type

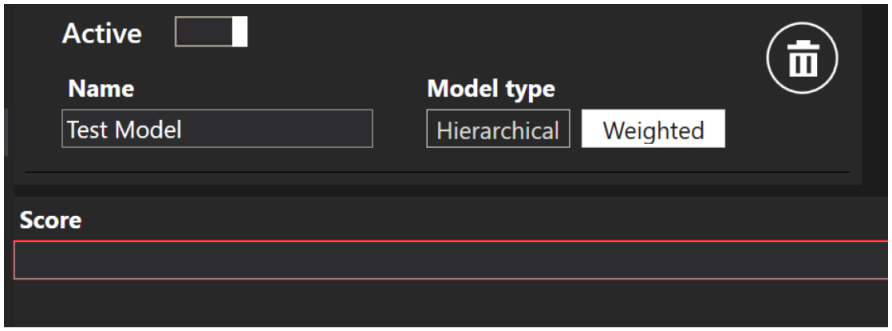


Figure 7.134 "Weighted" model type

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

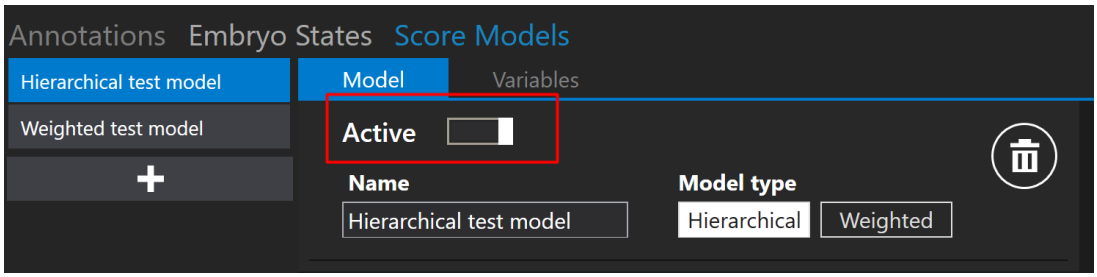


Figure 7.135 Activating or inactivating the selected score model

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.

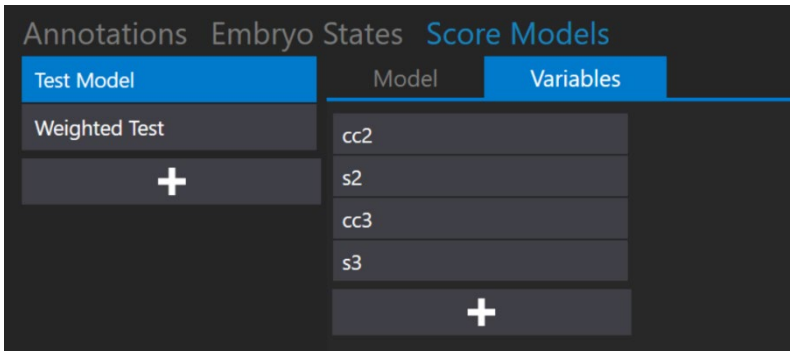


Figure 7.136 Listed "Variables" from the annotation list

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

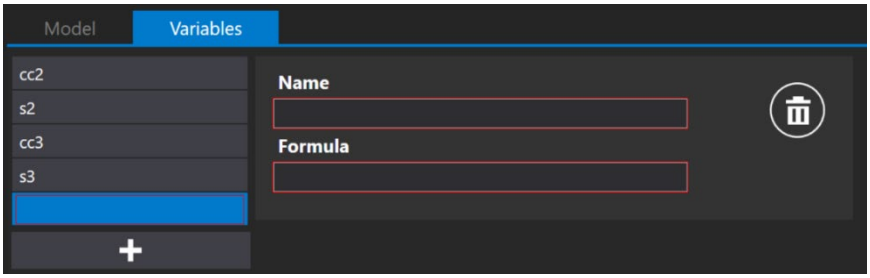


Figure 7.137 New variable creation

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.

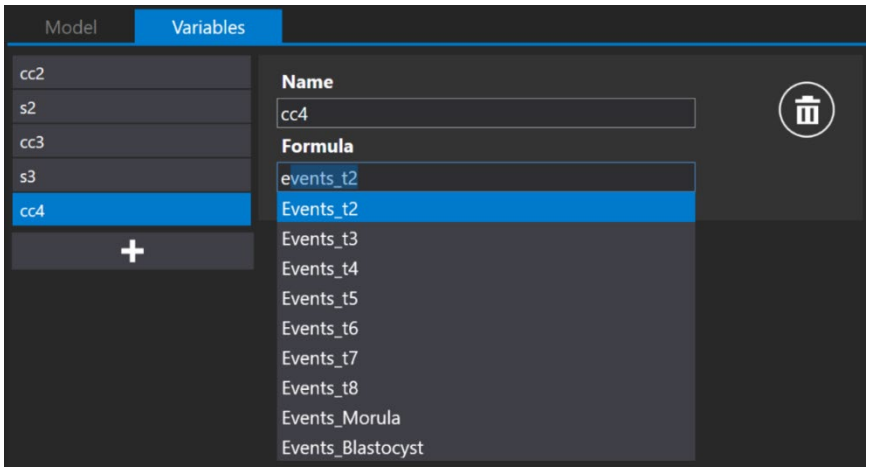


Figure 7.138 New variable creation

☞ 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).

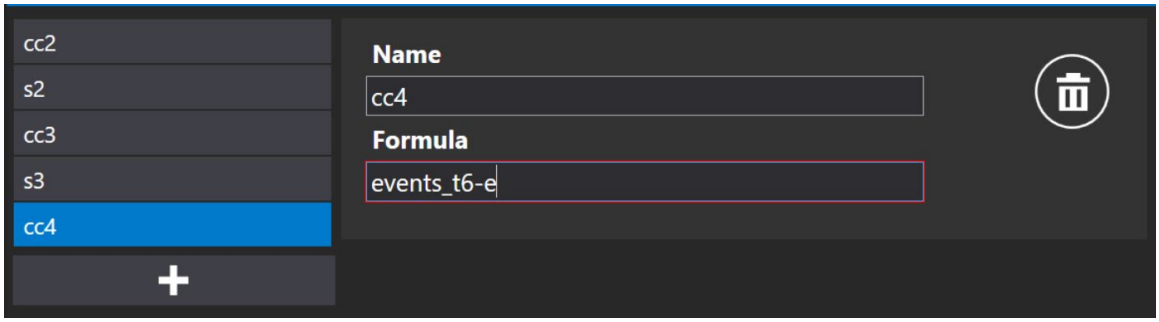


Figure 7.139 Formula creation without pressing the "Space" key

☞ The red square around "Formula" will disappear if the variable formula is written correctly.

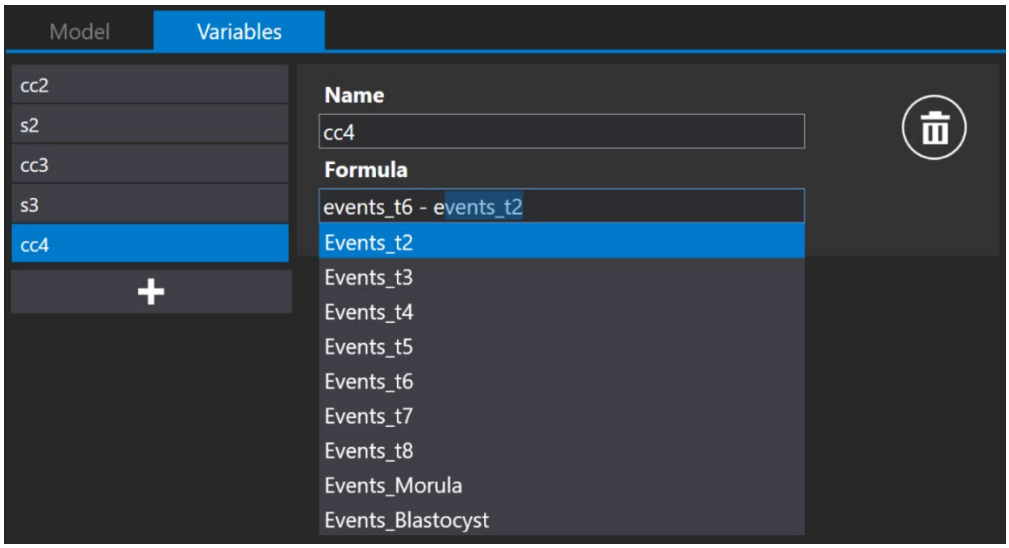


Figure 7.140 Formula creation when pressing the "Space" key

☞ 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.

7.6.3.1 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.

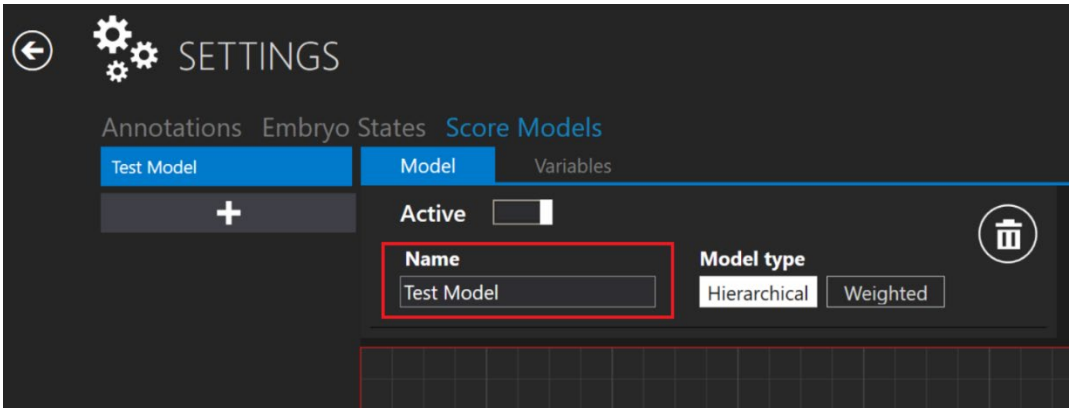


Figure 7.141 Naming the hierarchical embryo score model

7.6.3.1.1 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).

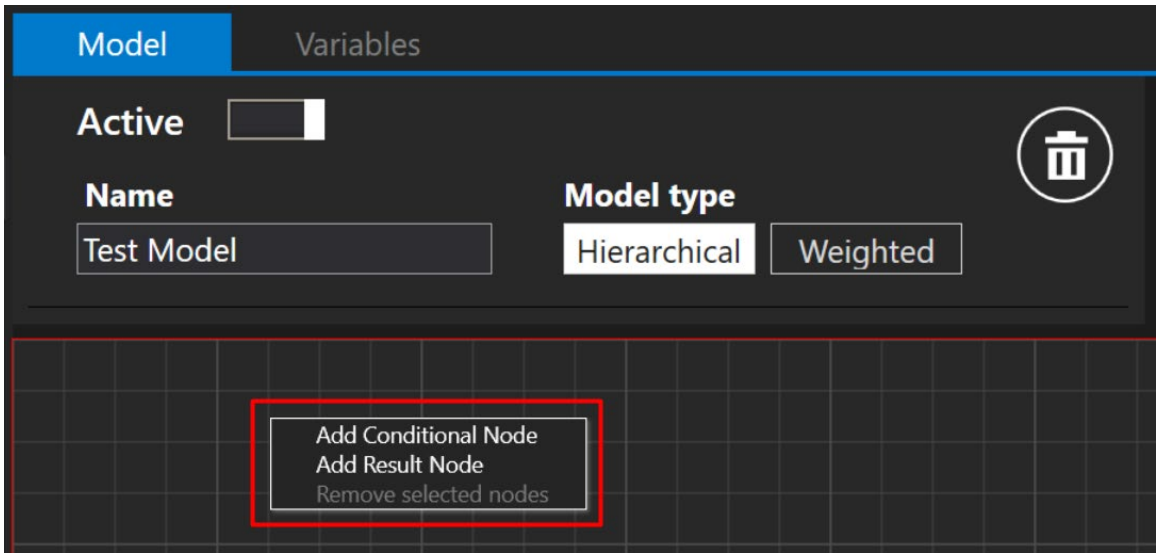


Figure 7.142 New conditional or result node creation

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

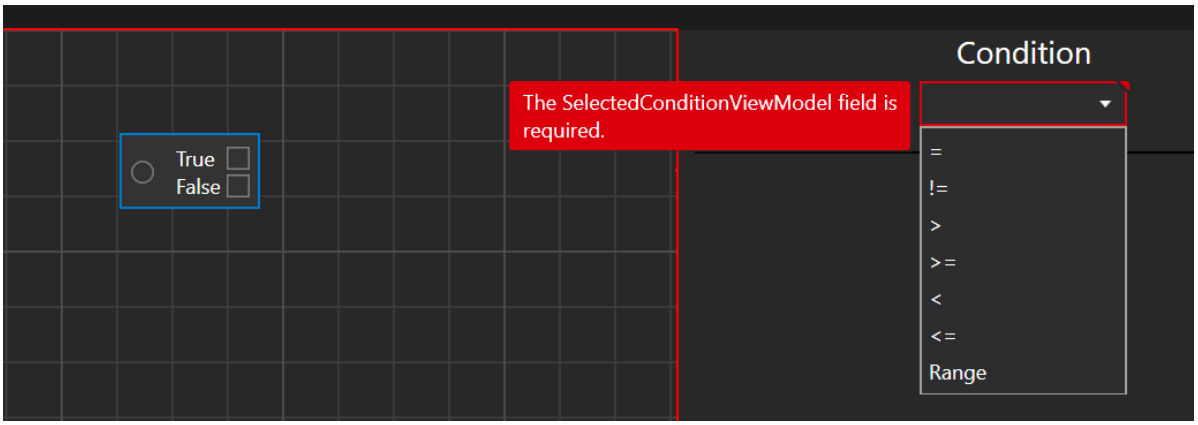


Figure 7.143 Available conditions

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!**

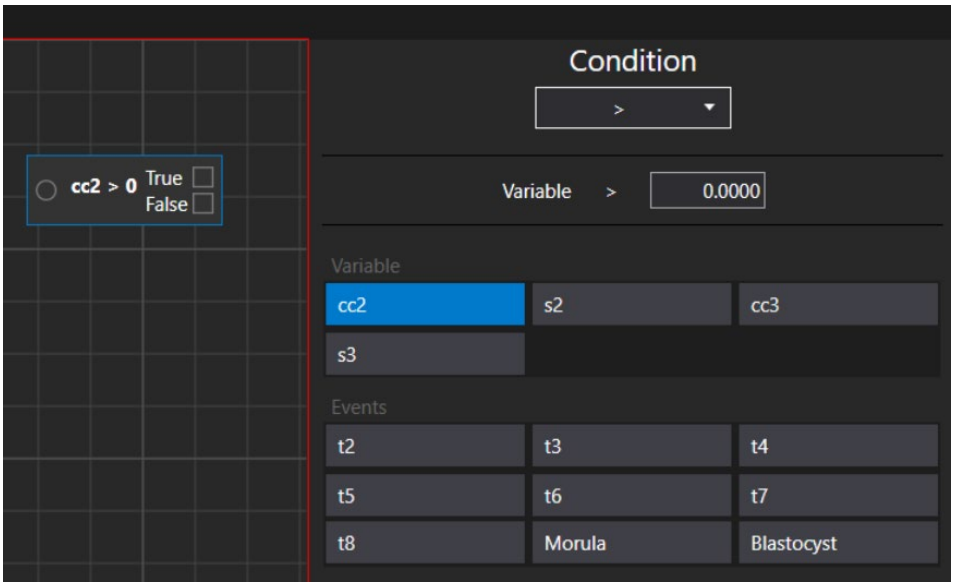


Figure 7.144 "More than" condition and annotation options

☞ **Only those annotations will be displayed which annotation group behavior is "Single" or "All".**

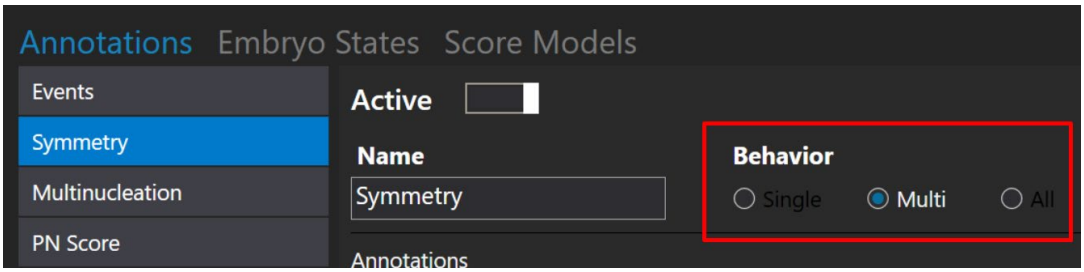


Figure 7.145 Possible annotations "Behavior" options

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.

7.6.3.1.2 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).

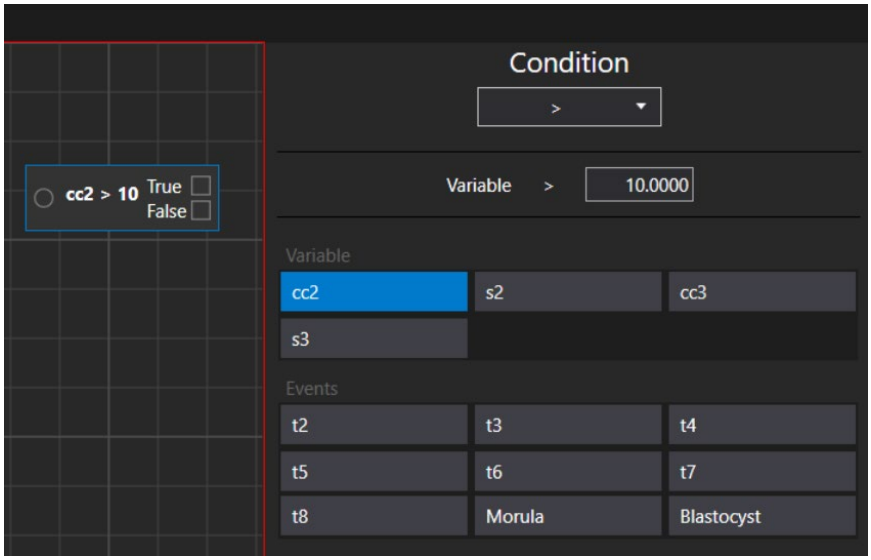


Figure 7.146 "cc2" variable is set to be more than 10

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.

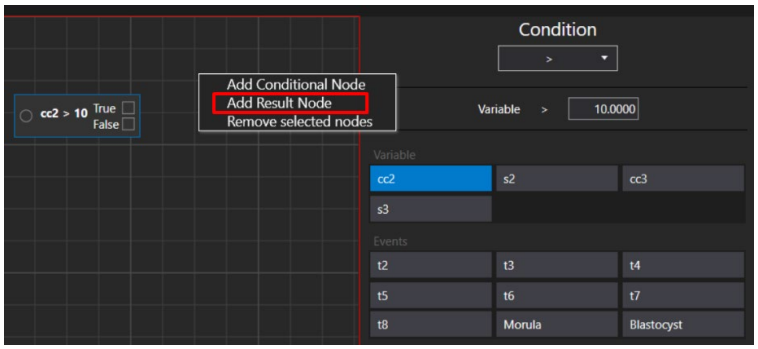


Figure 7.147 "Add Result Node" window

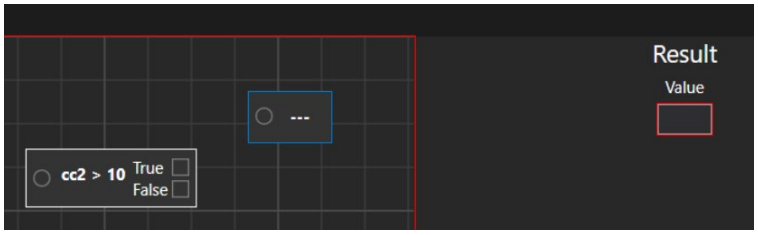


Figure 7.148 Created result node without set "value"

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 7.149 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 7.150 Conditional node with connected "Acceptable" result node

☞ The score model cannot be saved if the "Conditional Node" and "Result Nodes" are not linked. If the user tries to save it anyway, the "Score models has errors" message will appear.

☞ 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.

7.6.3.1.3 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.

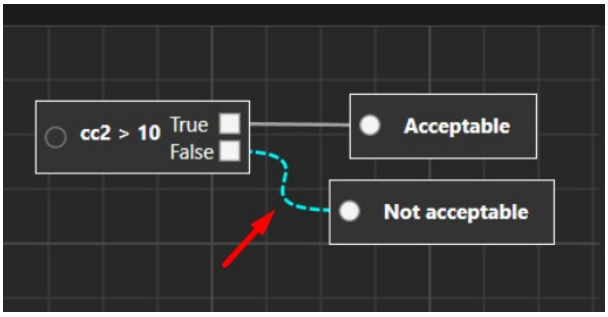


Figure 7.151 Removing the link between conditional and result nodes

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.

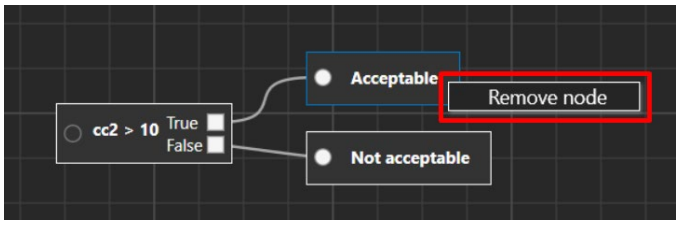


Figure 7.152 Removing "Acceptable" result node

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

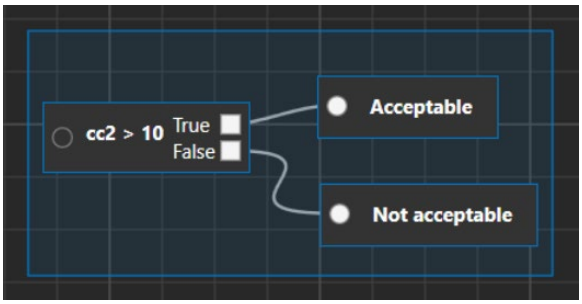


Figure 7.153 Selecting all the nodes

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 7.154 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.

7.6.3.1.4 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.

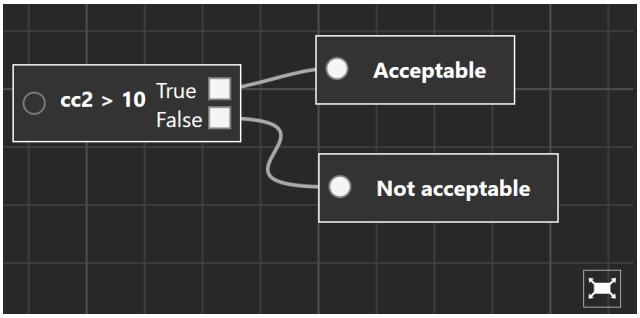


Figure 7.155 Maximized embryo score model view

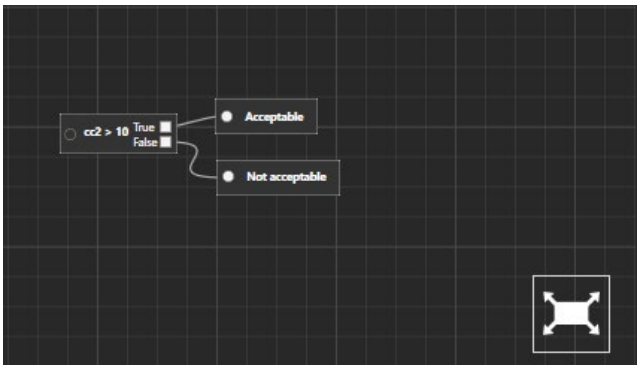


Figure 7.156 Minimized embryo score model view

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

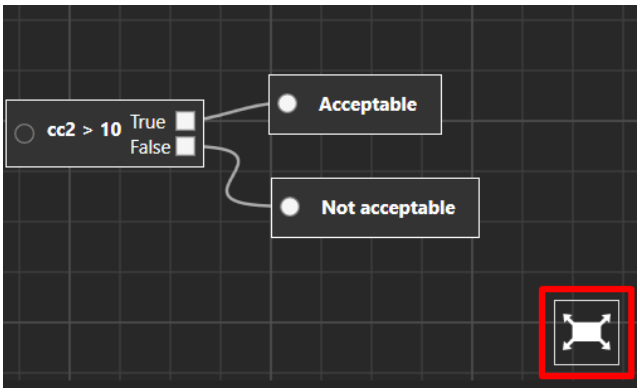


Figure 7.157 Resetting the initial score model view

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.

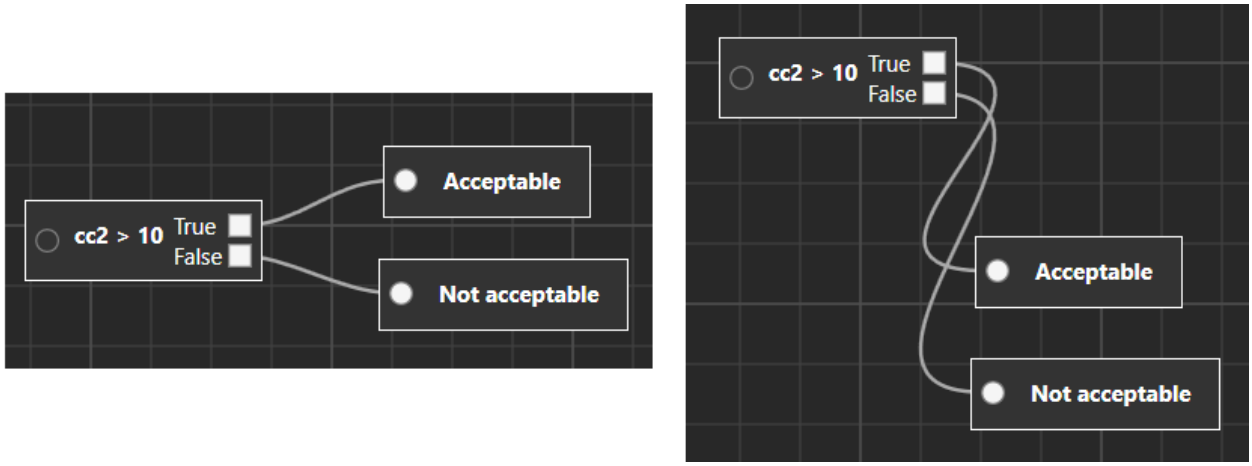


Figure 7.158 Moving the result nodes simultaneously

7.6.3.2 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.

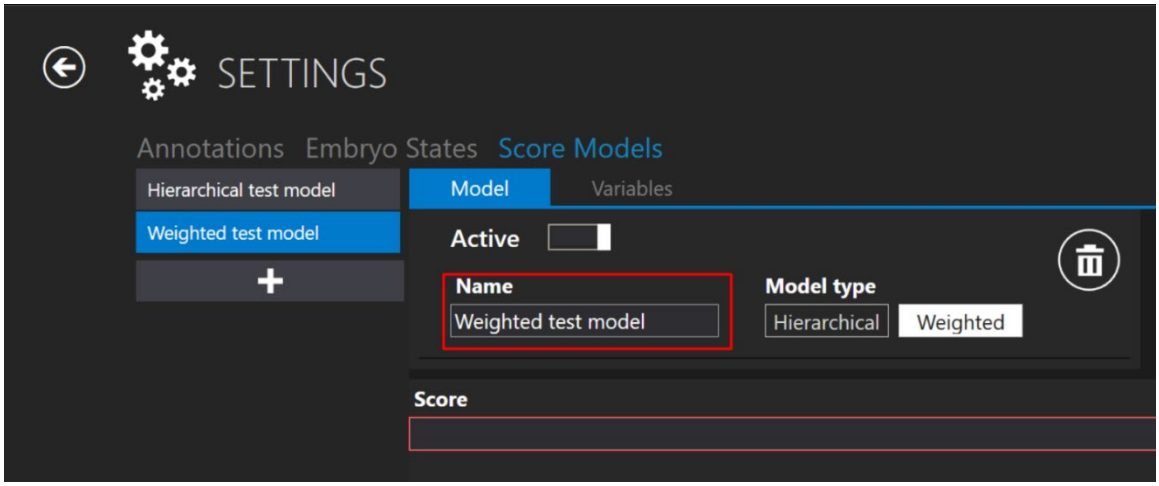


Figure 7.159 Naming the weighted embryo score model

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.

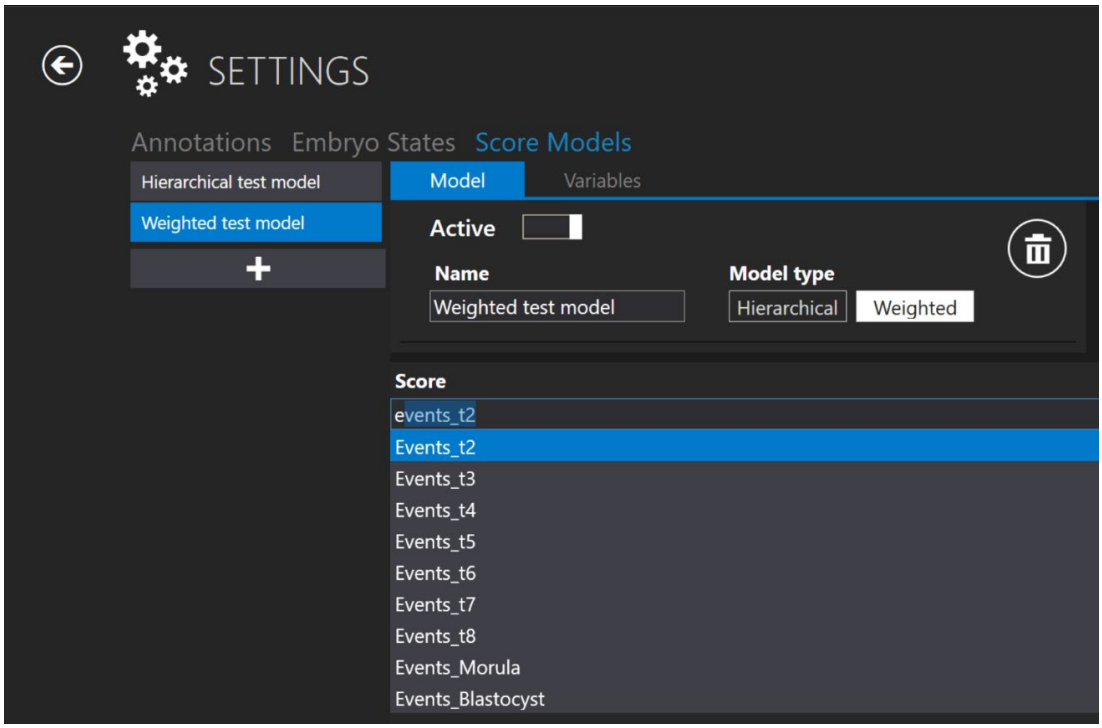


Figure 7.160 New score creation

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

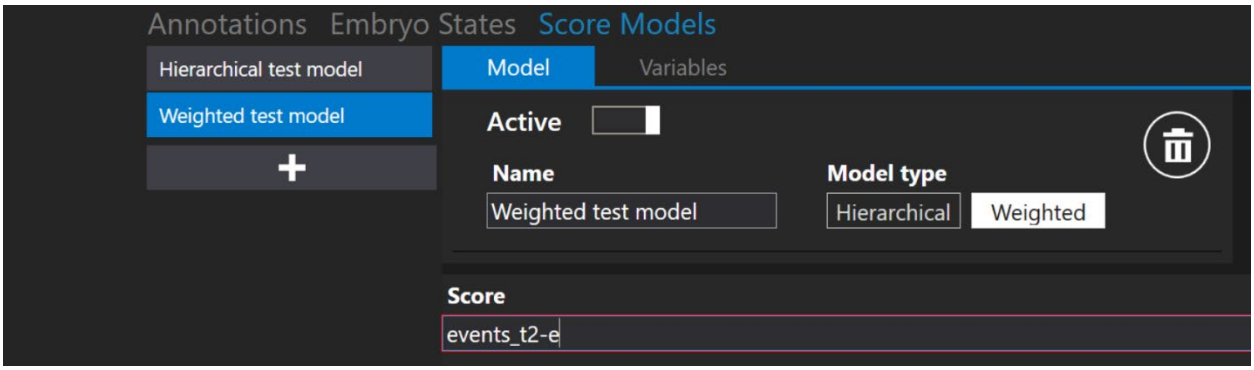


Figure 7.161 New score creation without using the "Space" key

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

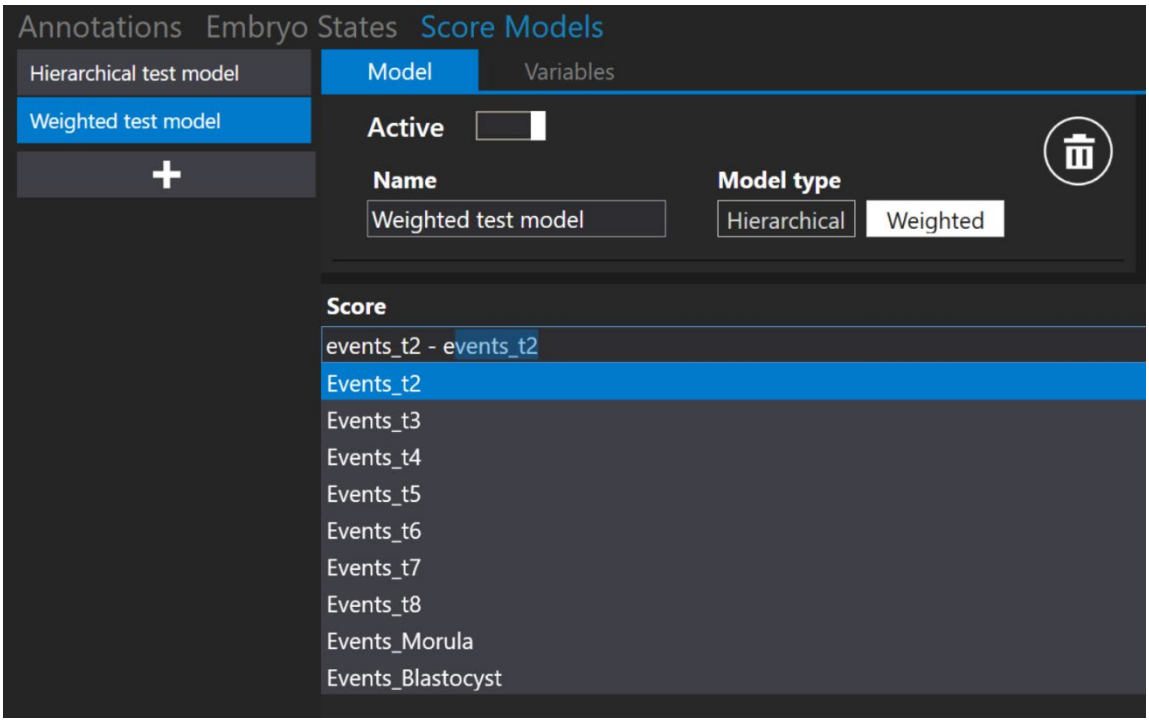


Figure 7.162 New score creation using the "Space" key

7.6.3.3 Deleting the score models

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

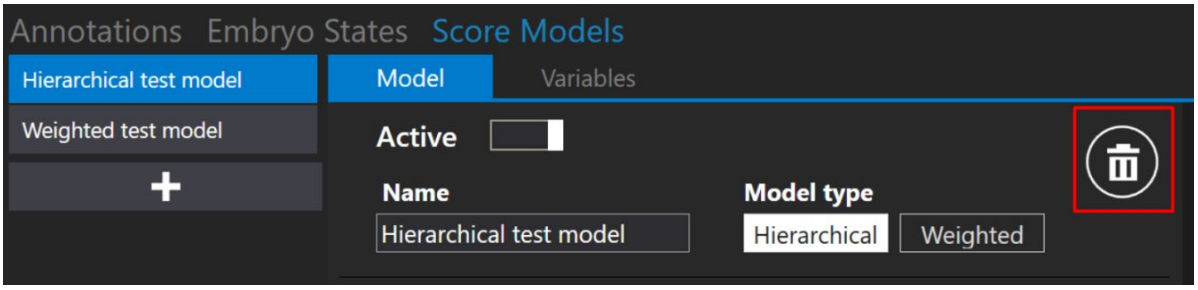


Figure 7.163 “Trash bin” button to delete created embryo score model

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.

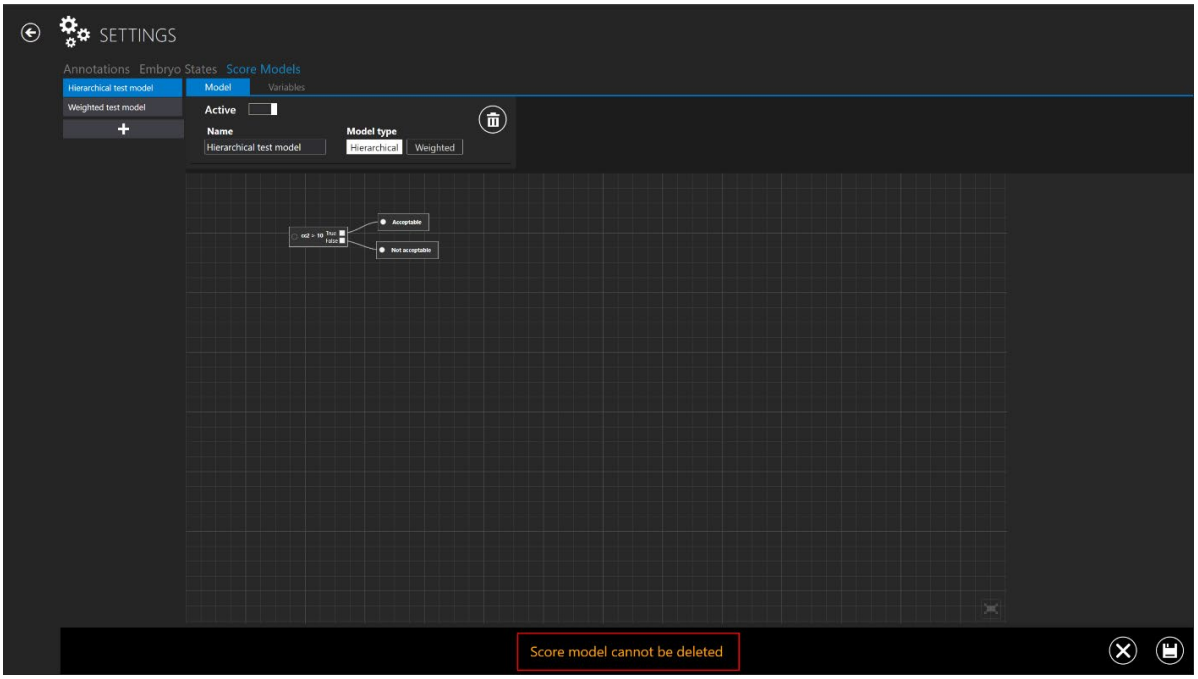


Figure 7.164 Error message when trying to delete embryo score model which is assigned to a timelapse

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

8 Technical assistance

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