

CE 0088




User Manual

MIRI® TL family's multiroom IVF incubators Viewer Software

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Rx only



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

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.

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 Indication for use

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

4 About the product

The Esco Medical MIRI® TL6 and MIRI® TL12 multiroom IVF incubator are a CO₂/O₂ incubators with time-lapse 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 time-lapse 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 compartment 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 – 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 – 24. They control and regulate temperature in culture chambers and lids. Compartments do not affect each other's temperatures in any way. The top and the bottom of each compartment is separated with a PET layer so that the lid temperature would not affect the bottom. For validation purposes, each compartment 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% CO₂ and 100% N₂ in order to be able to control the CO₂ and O₂ gas concentrations in the culture chambers.

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

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 compartment, whereas MIRI® TL12 – 12.

The multiroom IVF incubator features a recirculated gas system where gas is continuously put into the compartment 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 CO₂ and 5 l/h N₂ 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 compartment is easy to reach and safe because of the compartment 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 time-lapse 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.

A pH sensor port is part of the DAQ package. The user can plug any standard BNC pH probe to the unit and measure the pH in the samples at will.

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 time-lapse, 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 time-lapse 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.

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 $\geq 3.0\text{GHz}$
- 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
- $\geq 8\text{GB}$ 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.

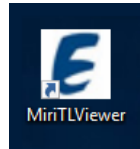


Figure 7.1 “MIRI® TL Viewer” icon on the desktop

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:

- Time-lapses (a list of the generated Time-lapses)
- 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).

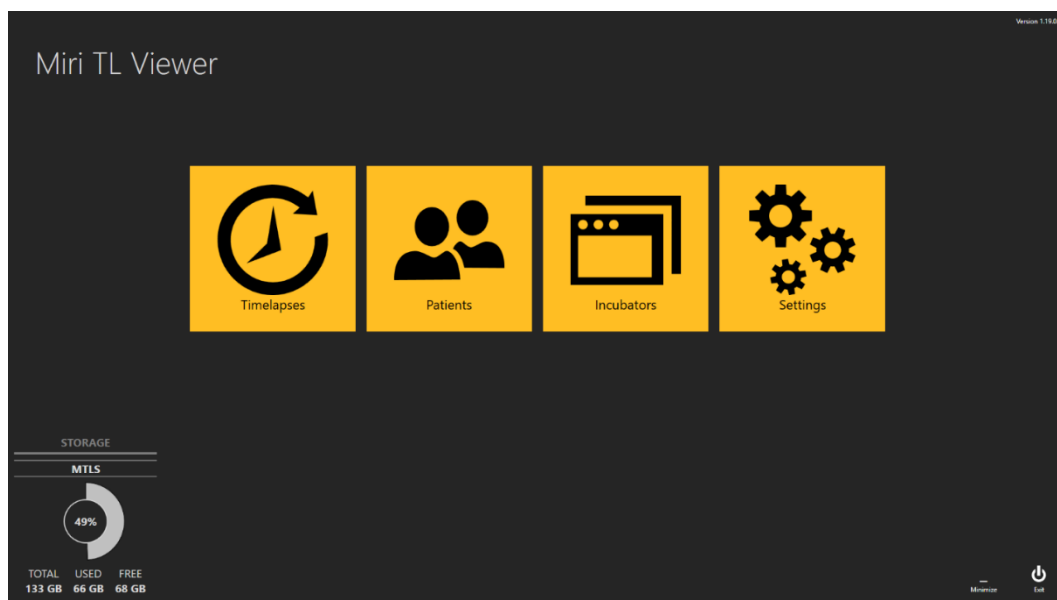


Figure 7.2 MIRI® TL6 and MIRI® TL12 multiroom IVF incubators Viewer main screen

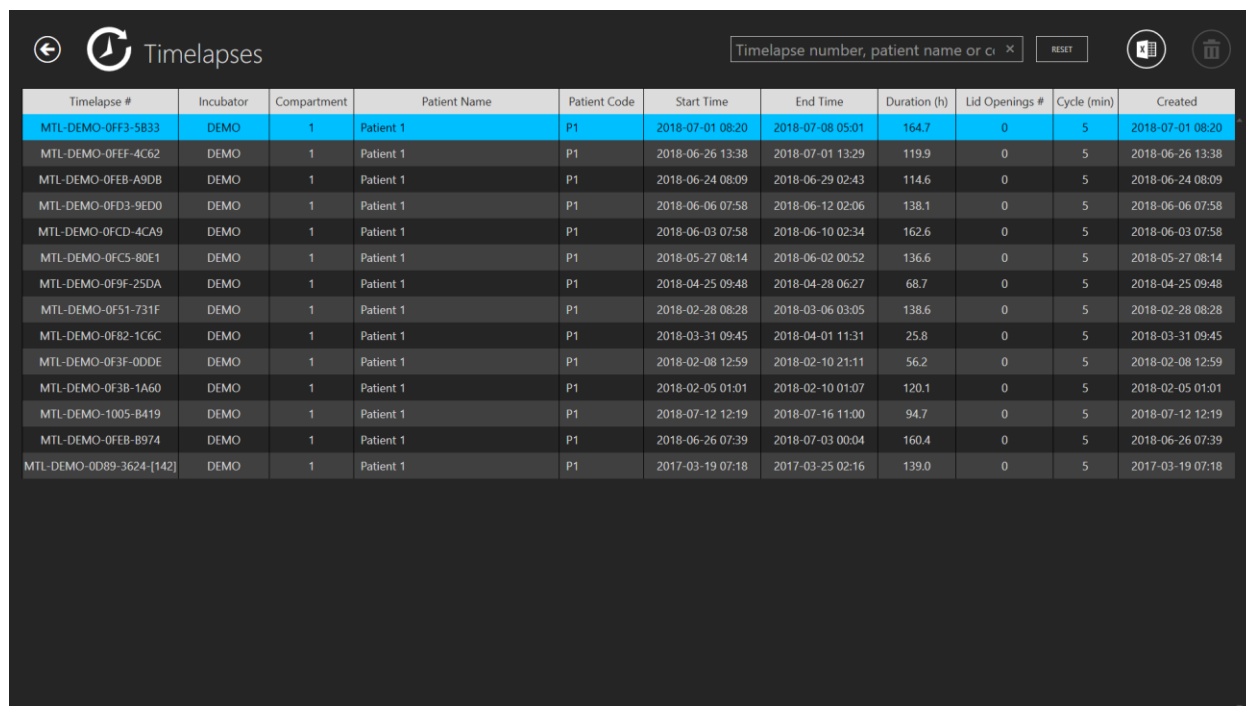
All interaction with the software is intuitive and straightforward. Navigation between the views is done by pressing the relevant colored icons or the back arrow in the top left corner.

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

7.3 Time-lapses

7.3.1 Time-lapse list view

Pressing the “Time-lapses” button changes the view to the list of the time-lapses 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-0F38-1A60	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-0DB9-3624-[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 time-lapses

A multiroom IVF incubator filter function is in the top left corner of the main display, where the user can narrow the time-lapse search by selecting the specific incubator.

The user can also narrow the time-lapse search by selecting the time-lapse state: “All”, “Active” or “Finished”.

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

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

The “Reset” button will reset all selected filters.

By pressing on a “Report” button in the top right corner of the main MIRI® TL family’s multiroom IVF incubators Viewer view, the user can generate a time-lapse annotation file.

The “Delete” button will delete the selected time-lapse. The user can delete the time-lapse 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 time-lapse.

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

The time-lapse view shows:

- Time-lapse number (unique time-lapse identifier)
- Multiroom IV incubator (in which MIRI® TL multiroom IVF incubator the specific time-lapse was generated)
- Compartment (in which MIRI® TL6 or MIRI® TL12 multiroom IVF incubators compartment the specific time-lapse 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 compartment during the time-lapse)
- Cycle (min) (the set cycle time between each image stack)
- Created (the date and time when the time-lapse file was created)

7.3.3 Time-lapse view

A time-lapse data file is opened either from the main time-lapse list view, from the specific patient view or the specific patient treatment view.

A revolver view with the movie files will open.

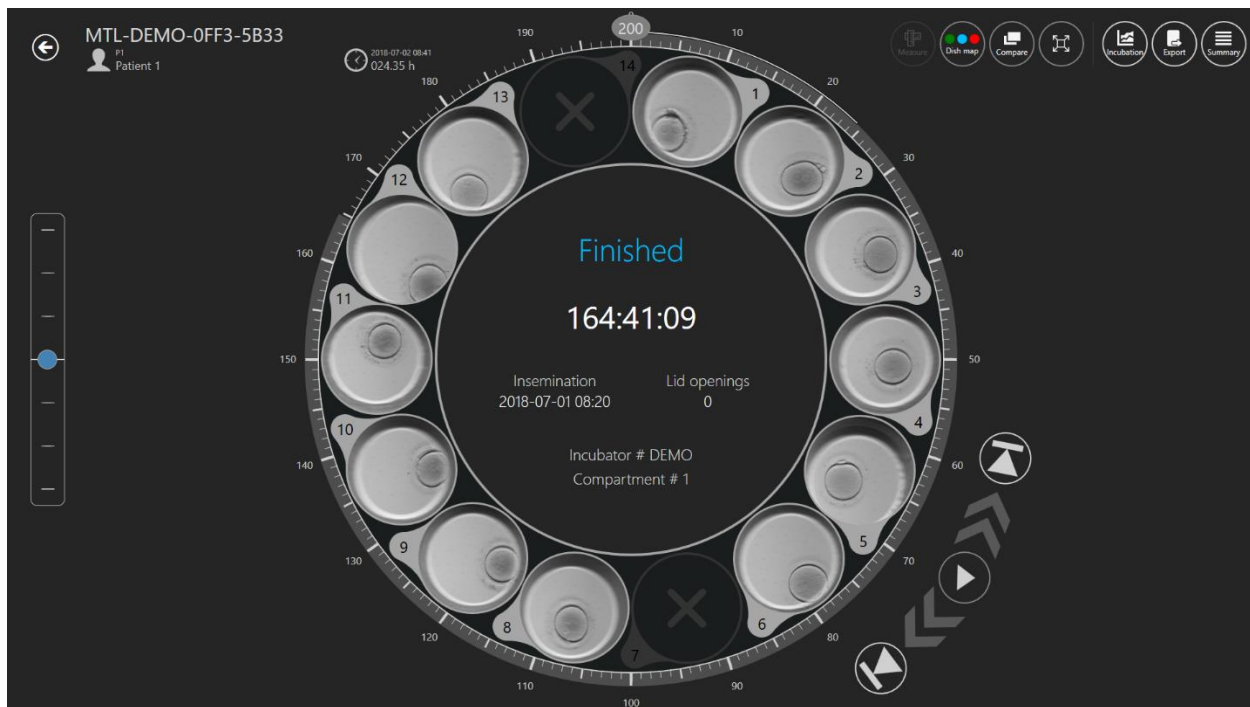


Figure 7.4 The time-lapse view of a specific patient

The view contains the 14 wells of one single CultureCoin® dish. Sometimes the well can be displayed as inactive (see User Manual of MIRI® TL family's multiroom IVF incubators), and the user will not select it. In figure 7.4, wells 7 and 14 are inactive. When the well is active, the user can select it, and it will be displayed in the middle of the revolver view. By clicking on the well-used not only enlarges the well view but also enables features like annotation, measurement, comparison, etc.

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

- Incubator number
- Compartment number
- Insemination time
- Lid openings during the time-lapse

- A status: “Pending” or “Finished”

In the upper left corner of the Time-lapse view, the time-lapse ID number and patient information are provided.

To the left of the Time-lapse view, there is a focal plane shifter. It will have the number of steps the time-lapse movie was generated in (i.e., 3, 5 or 7). Move the blue marker up and down to shift all movies simultaneously through the focal planes. Focal planes cannot be shown differently for discrete wells. All 14 wells will be at the same focal plane at all times.

To the right, just near the wheel, 5 video player controls are located. They enable the user to move through film, pause, play or jump to the start or end.

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 revolver view, near the 13th well.

7.3.3.1 Annotations

The annotation system is structured around “Events” located to the left of the wheel and only when an embryo is in the active area.

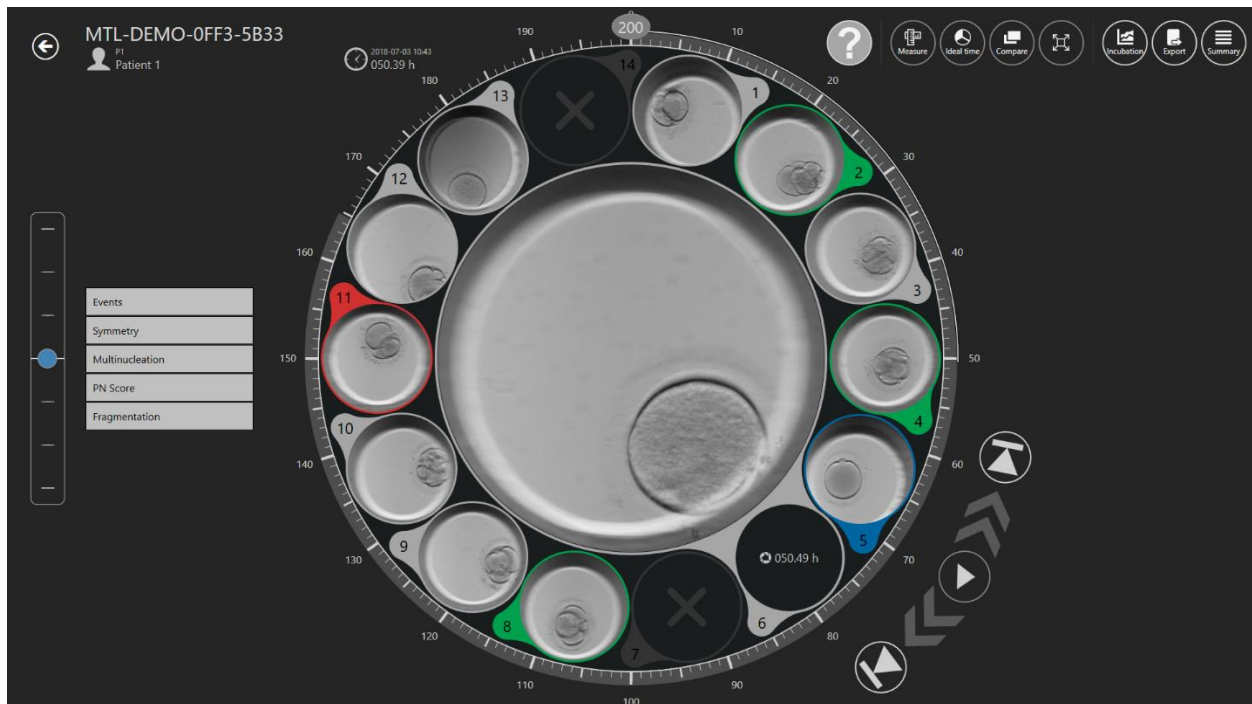


Figure 7.5 Time-lapse annotations view

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. Now the t2 will move to the Time-lapse view's right side, and the timeline until the event will be colored with appropriate annotation color. When all events have been assigned a time, the embryo has been annotated. How many events the user wants to use (level of annotation) is entirely at their discretion and dependent on the selection criteria that the clinic use. 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 (See section 7.6.1 for more details).

In the default form it contains:

- 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)

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, cell cycles time difference between certain cell divisions, i.e., $cc2 = t3 - t2$; $cc3 = t5 - t3$.

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

Figure 7.6 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 assigned a time and moved to result (annotated).

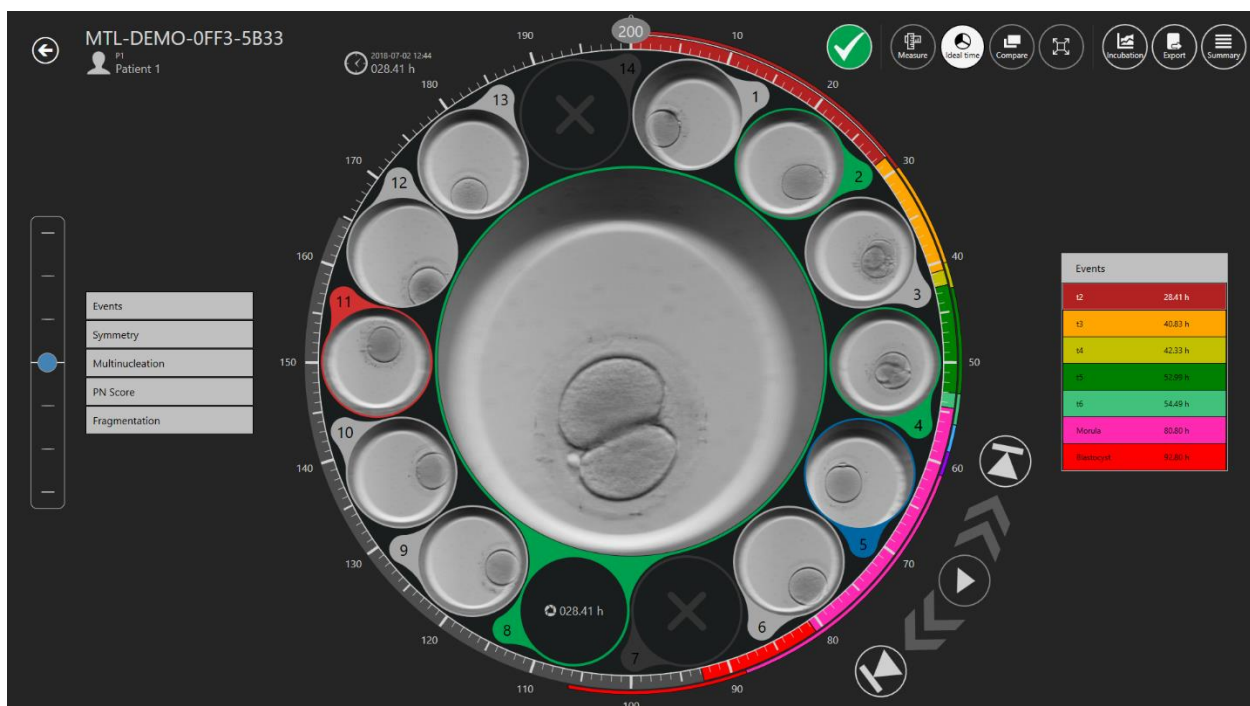


Figure 7.7 Selected “two cells” event annotation

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 user can create additional embryo states. More information is provided in the “7.6.2 Embryo states” section.

The assignment is done on the icon at the top right.

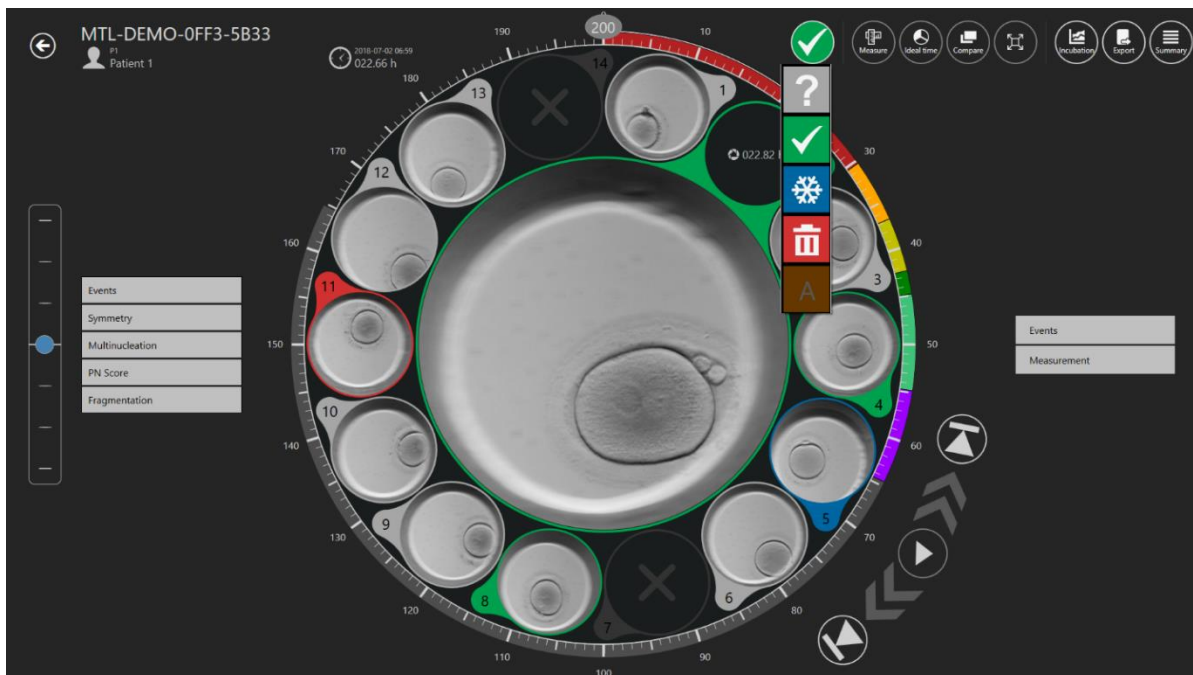


Figure 7.8 The embryo status selection

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.

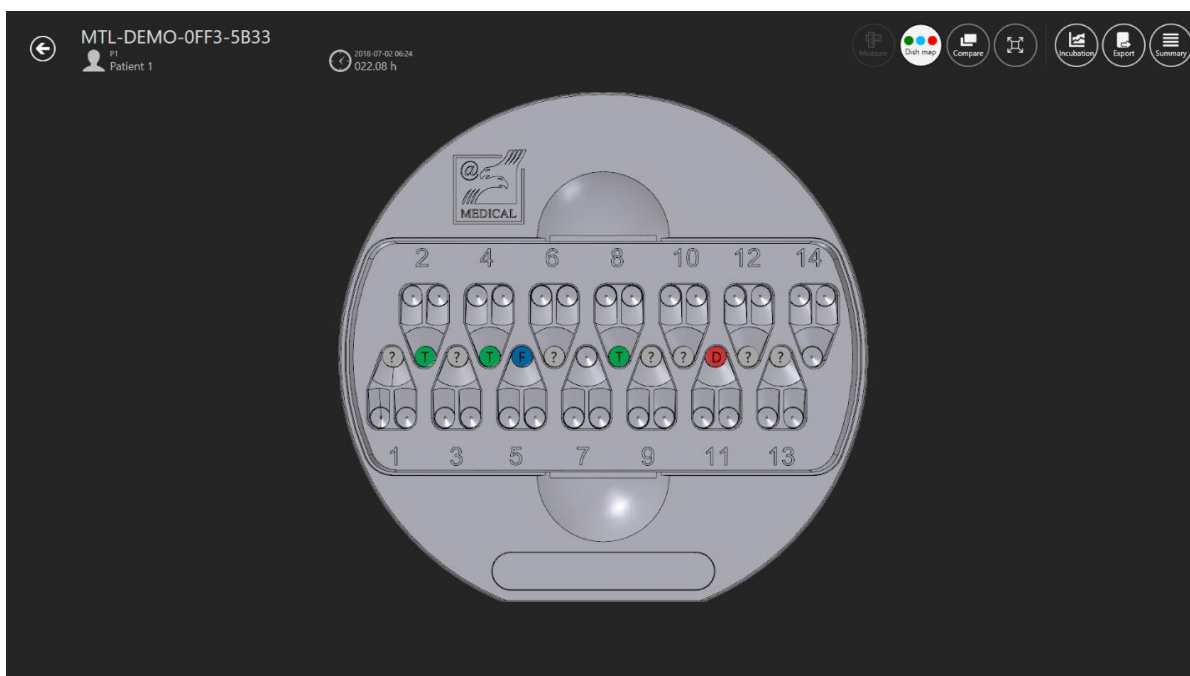


Figure 7.9 The dish map

7.3.3.2 Embryo measurement function

There is a “Measure” button in the upper right corner of the main time-lapse view. Only when the desired dish well is chosen, the “Measure” button will be activated. Otherwise, the button will be inactive.

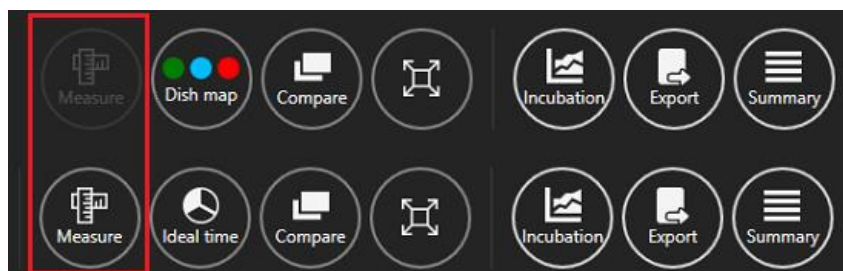



Figure 7.10 Active and inactive “Measure” button on the MIRI® TL Viewer

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



Figure 7.11 Three measurement options

There is a possibility to choose from 2 lines and 1 circle measurement. It is also possible to select the color for the desired embryo measurement.

 **When the 3 measurement option appears, the user can not make annotations and the previous functions will be unavailable.**

In the picture below, 3 added measurements can be seen on the desired time-lapse image.

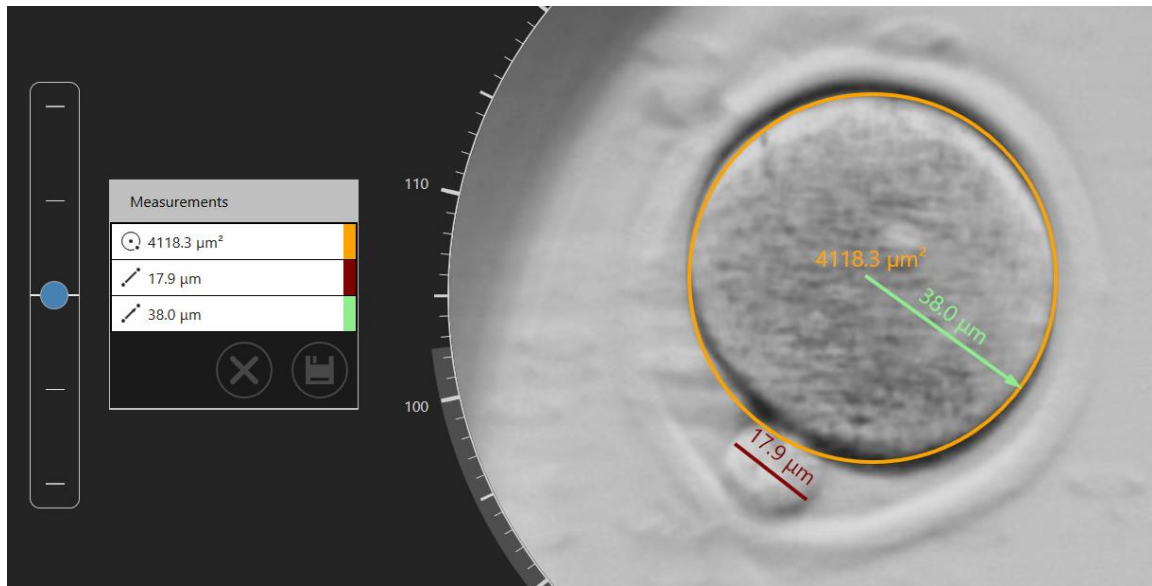



Figure 7.12 Added measurements on the time-lapse image

There is a possibility to delete the unwanted measurement by double-clicking on it. Pressing on the “X” button will delete all of the measurements.

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

 **When a measurement is created, or an existing one is adjusted, the user cannot change the displayed time (time slider is inactive) until the changes are saved or canceled.**

Measurement	
Measurement	5.27 h
Measurement	16.04 h

Figure 7.13 Measurements done at a specific time

7.3.3.3 The dish map

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

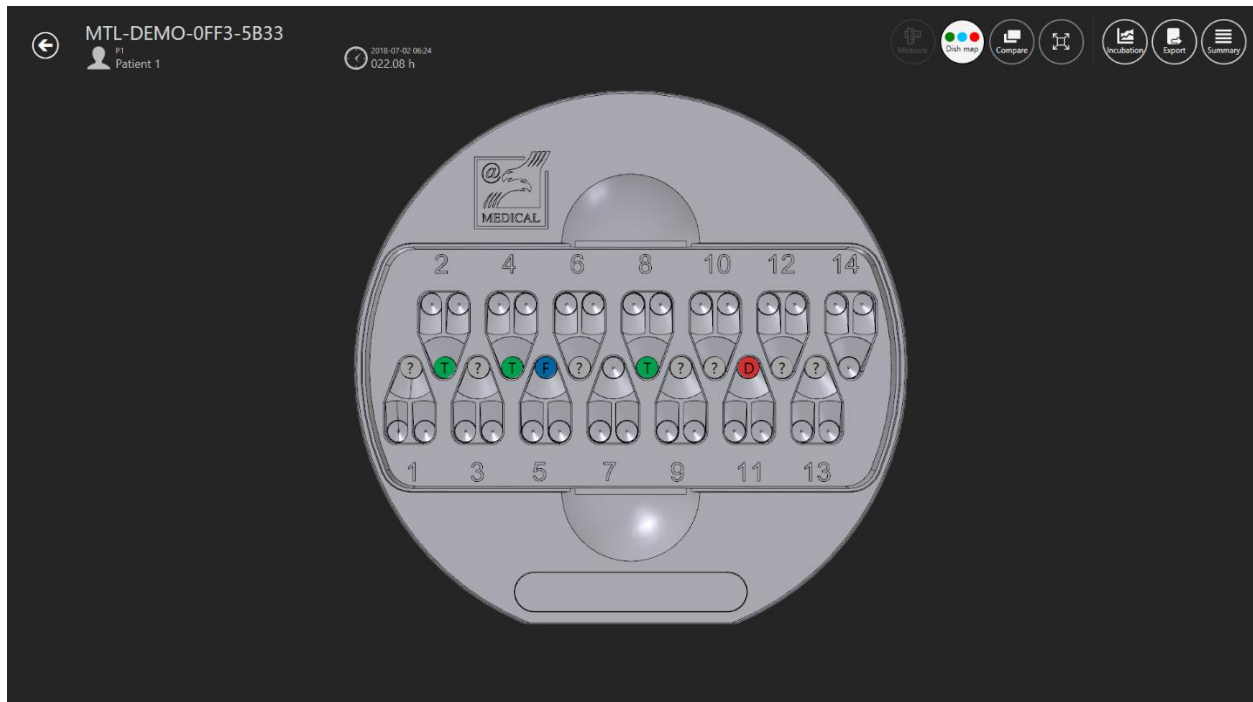


Figure 7.14 The dish map

Green means that the embryo is suitable for transfer, red for discard, blue for freeze and the “?” mark means that the user did not choose the embryo state.

7.3.3.4 Ideal time

The ideal time button turns “ON/OFF” a ring around the revolver wheel that colors the “Ideal” time length of a specific event (shown in Figure 7.15 below).

For instance, if t2 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 more the time point where the parameters match, the more ideal the embryo.

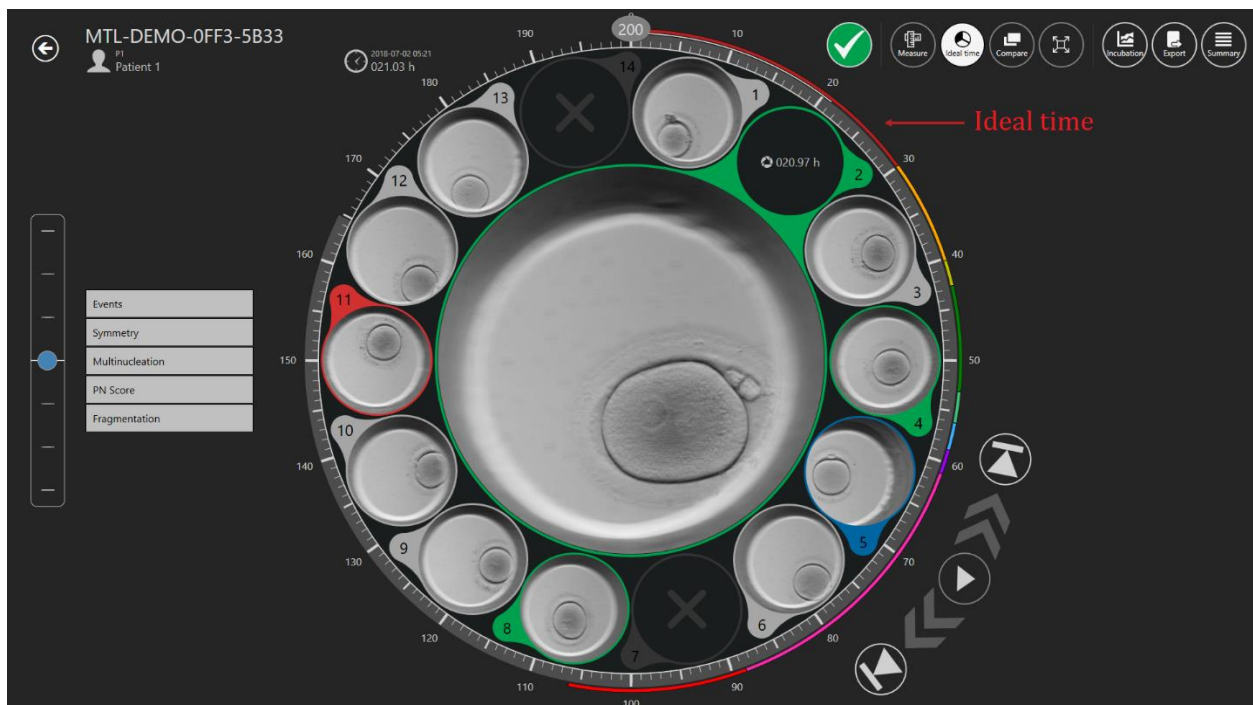


Figure 7.15 The ideal times shown around the revolver

The user sets up the ideal times as the parameters may differ for different clinics due to differences in working methods.

Please read more in the “7.6.1 Annotations” section for more guidance on how to change a specific event's ideal times.

7.3.3.5 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 decision. Click the “Compare” button, then select one well (if the well is already selected). It will be displayed in the center. Then choose another well you are interested in from the rest. Selecting the second well will display the Compare view.

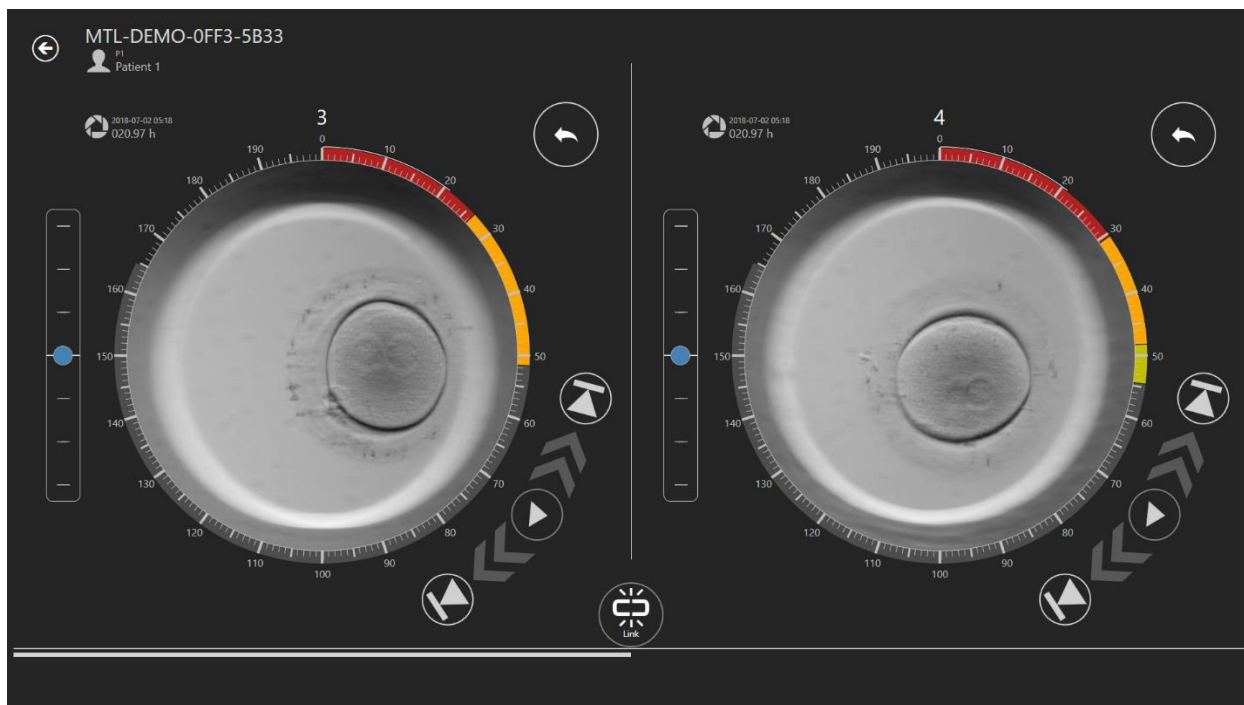


Figure 7.16 The independent “Compare” view

The two video players can be played independently or linked.

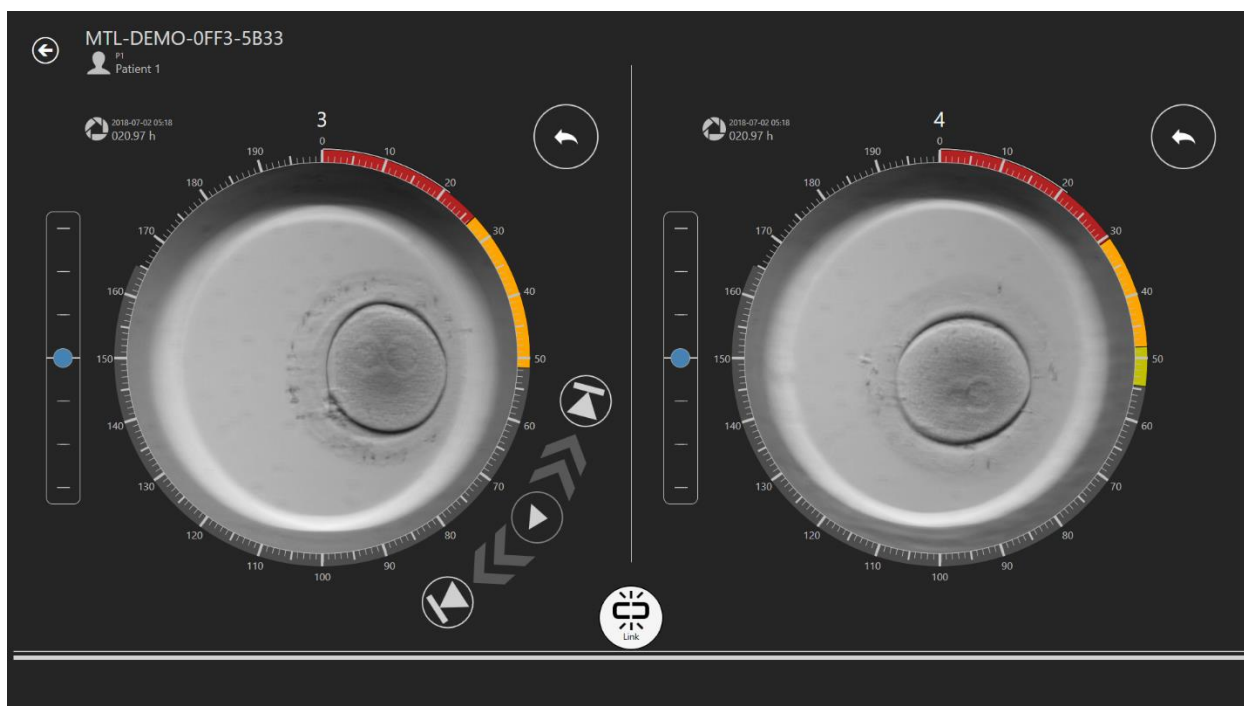


Figure 7.17 The linked “Compare” view

When they are linked, playback controls on the right side disappear.

7.3.3.6 Image maximization function

The “Maximize” button will increase the selected image in the center of the revolver.

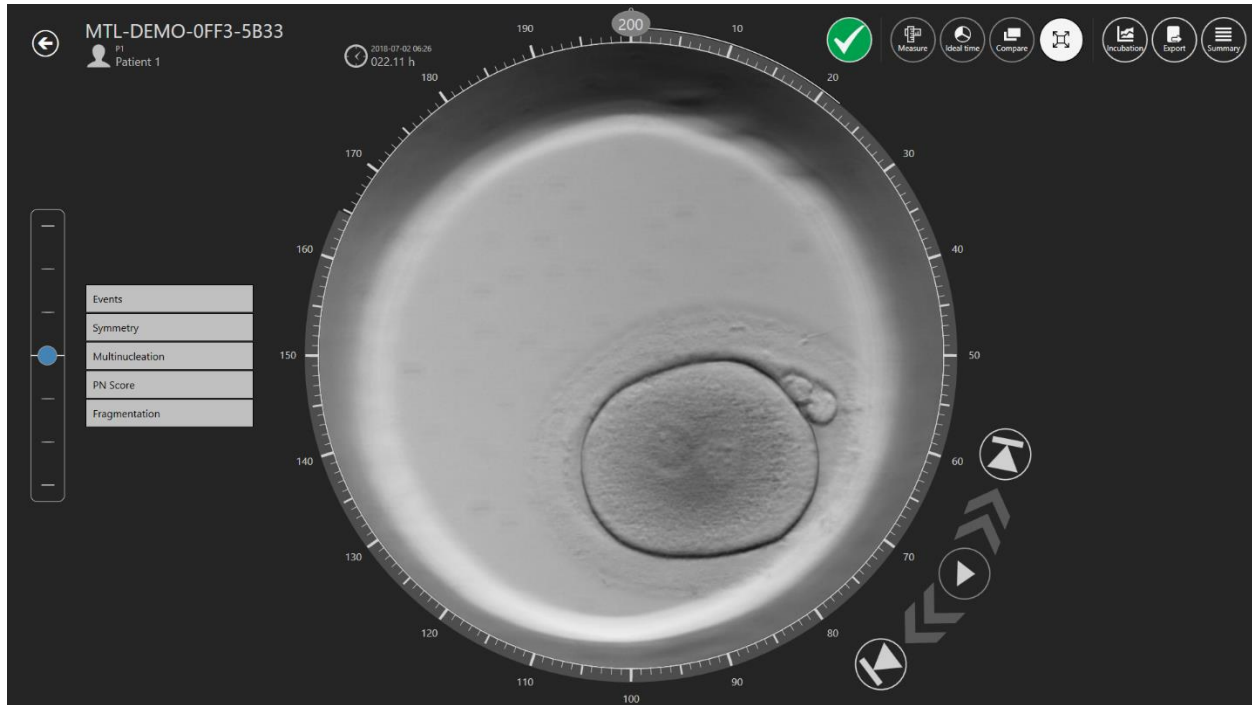


Figure 7.18 The “Maximize” view

7.3.3.7 Incubation data logging function

The “Incubation” button shows the incubation data for the MIRI® TL family’s multiroom IVF incubator CultureCoin® was or is. Incubator incubation data is displayed here when the time-lapse was performed.

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

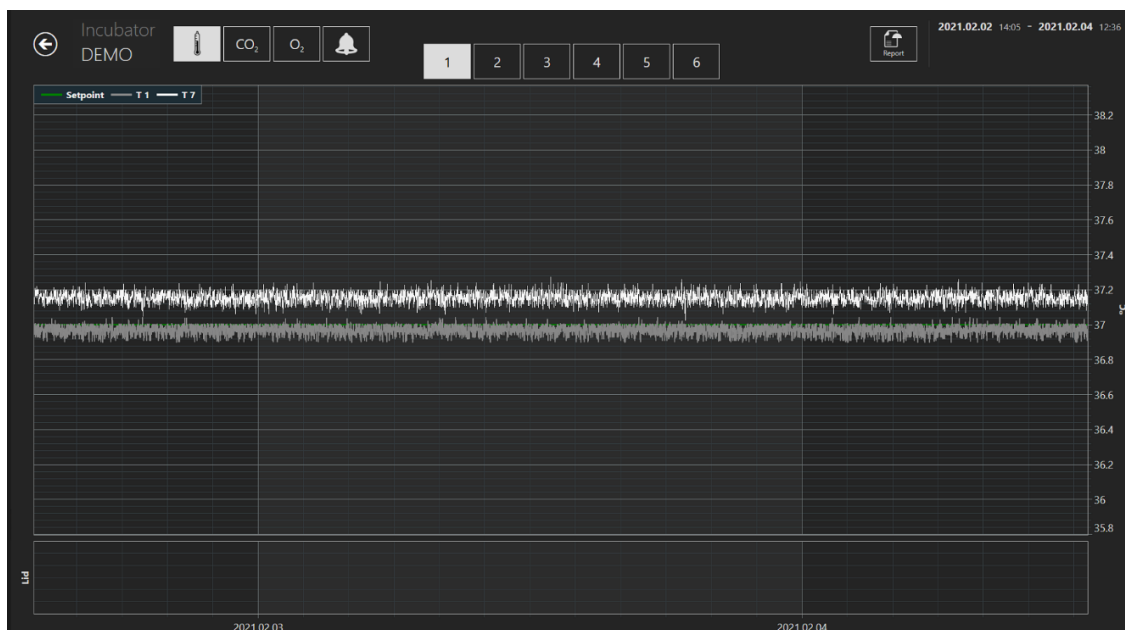


Figure 7.19 Temperature incubation view

At the top, there are buttons from 1 to 6, where the user can choose the desired compartment. In this case, compartment number 1 is selected. It will show the setpoint, T1 and T7 zones temperature values.

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

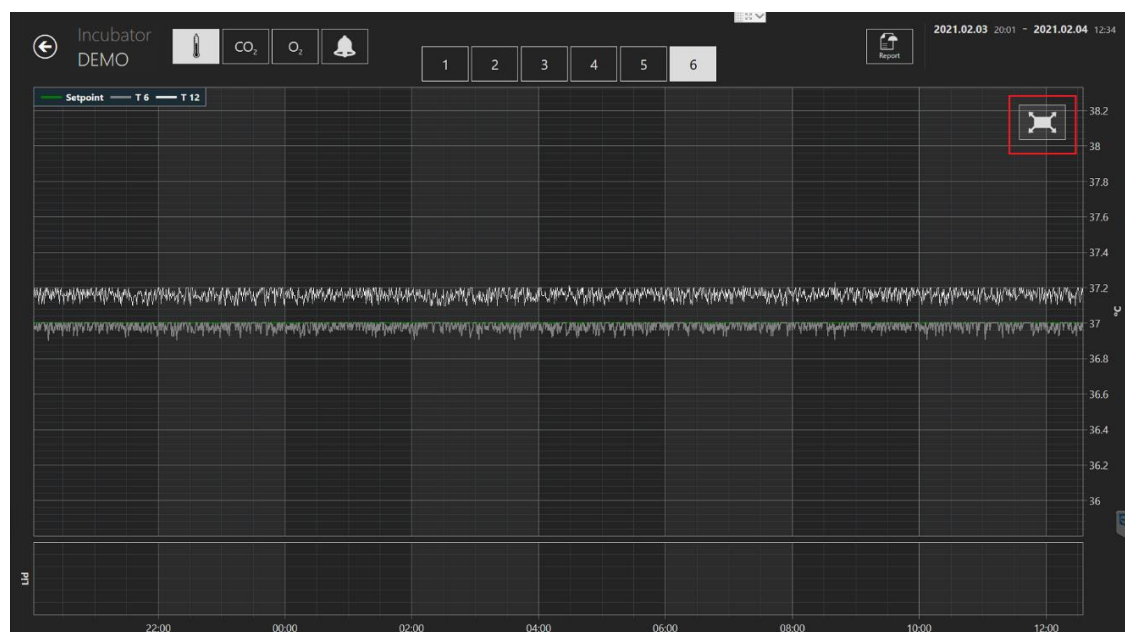


Figure 7.20 The reset button

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

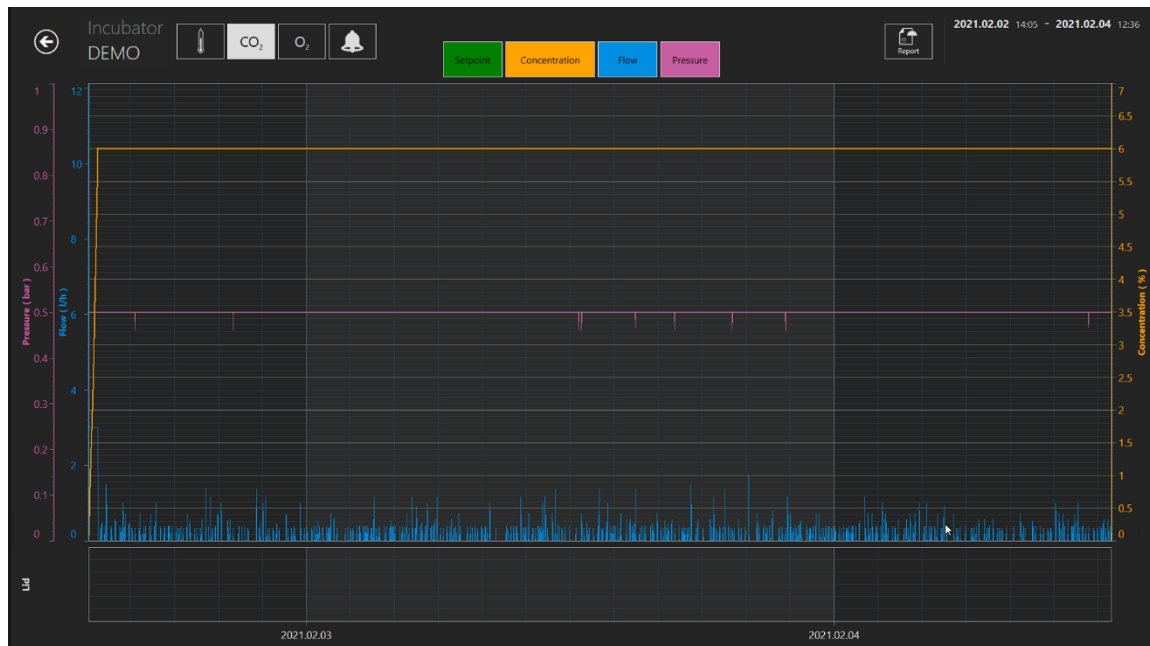


Figure 7.21 The CO₂ data view

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

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

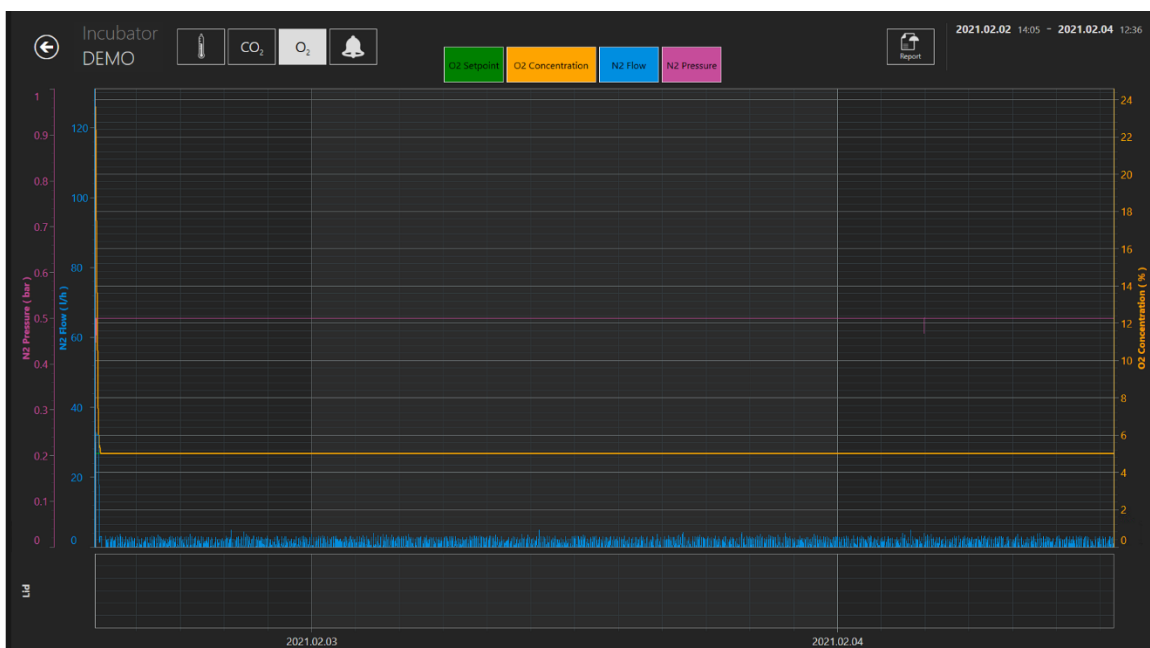


Figure 7.22 The O₂ data view

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

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

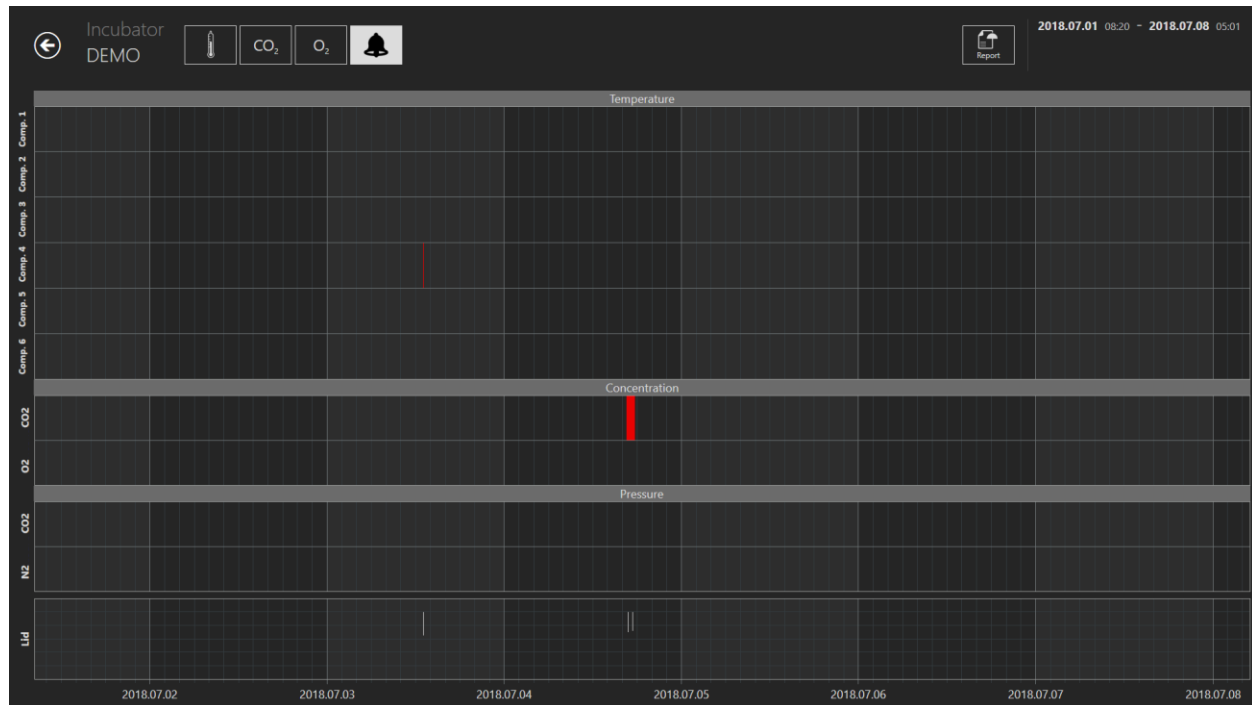


Figure 7.23 The graphical “alarm” view

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

7.3.3.8 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.

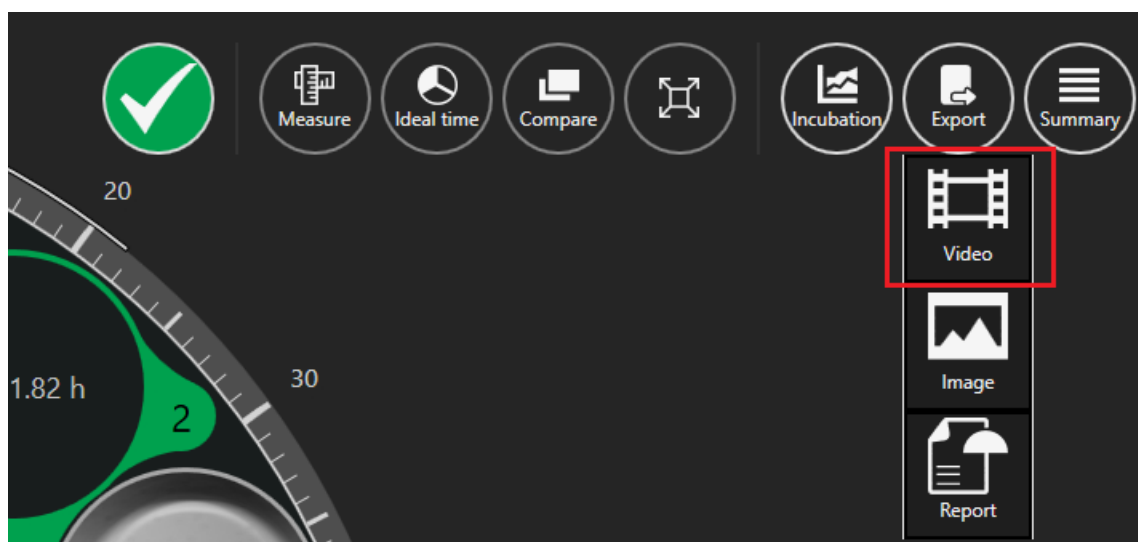


Figure 7.24 The “Export” option view

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

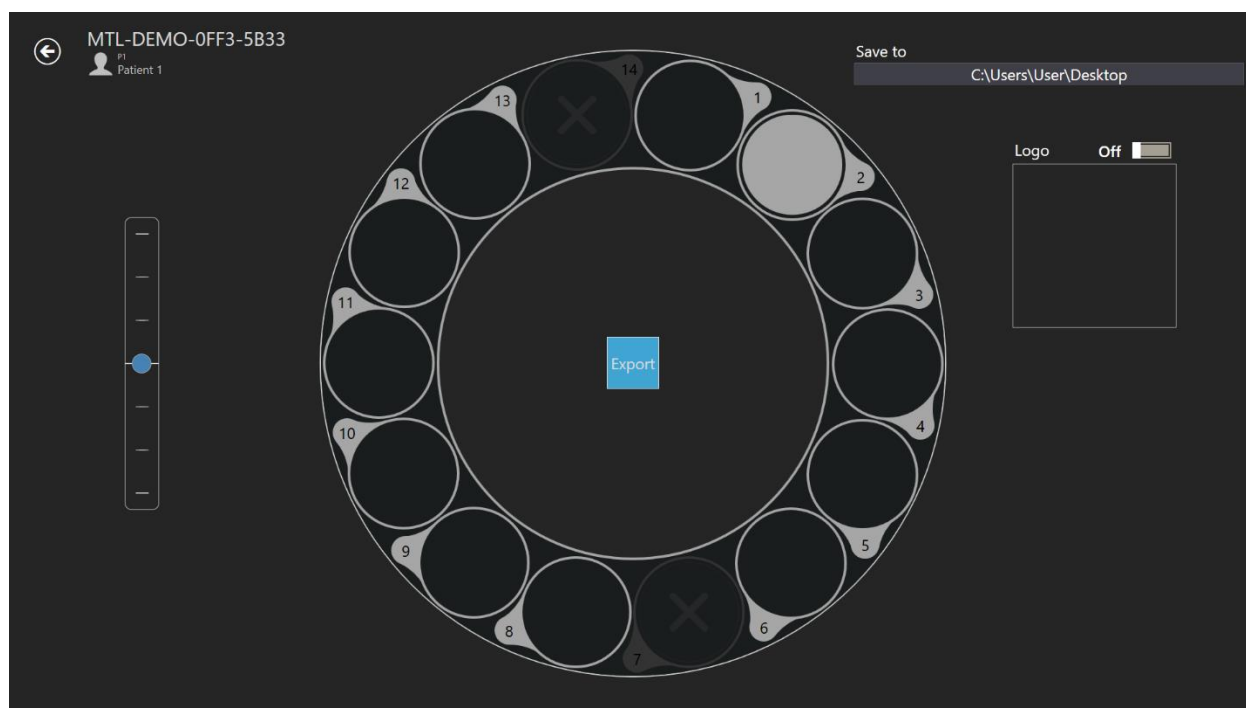


Figure 7.25 The video export view

The time-lapse video that the user wants to export can be selected here by clicking the desired well number. In the picture above, only the 2nd 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/>). Windows media player does not work. It is due to codec restrictions from Microsoft.

 **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.

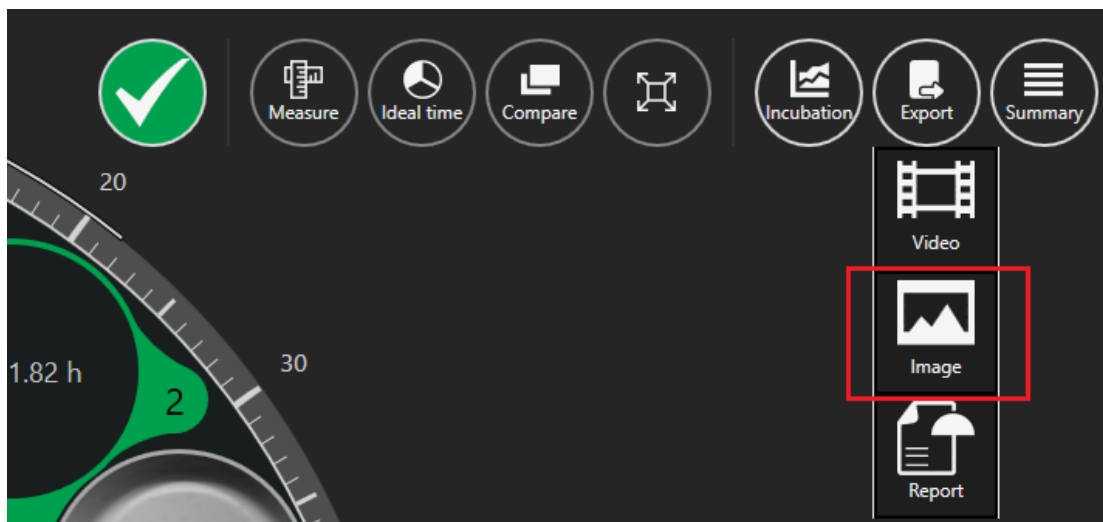


Figure 7.26 Selected image exportation button

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

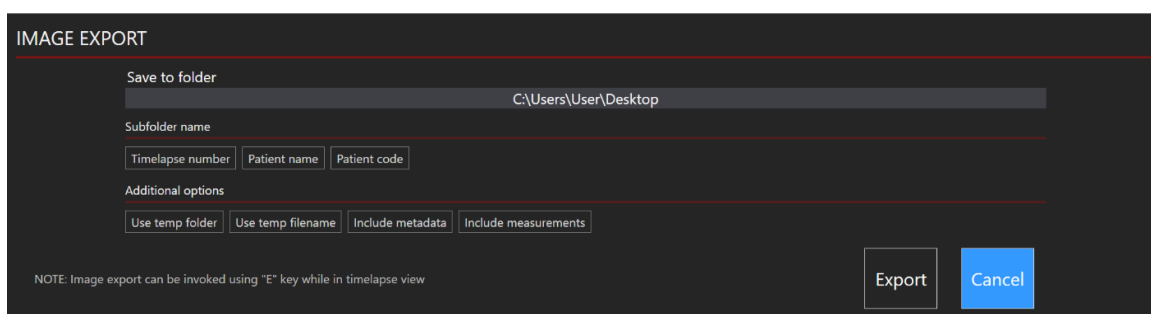


Figure 7.27 All options are inactive

The user can choose which information it wants 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 Time-lapse 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 be invoked using the “E” key on the keyboard.

Figure 7.28 “Include measurements” option active



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



Notice that the image name does not automatically change, 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.

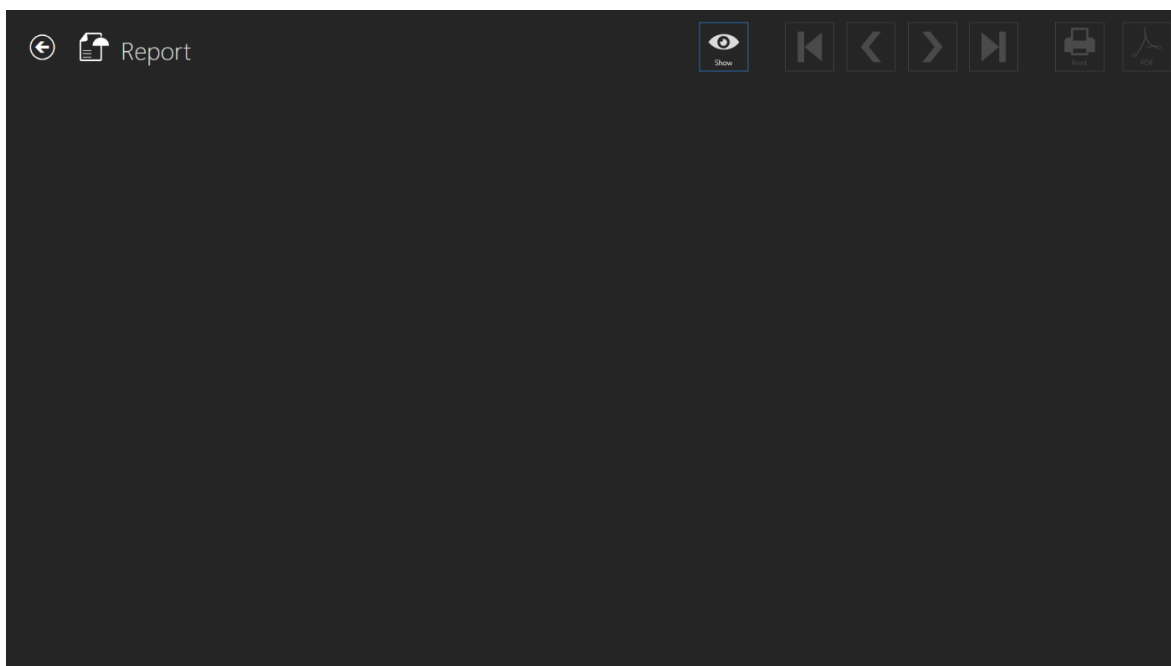


Figure 7.29 “Report” view

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.

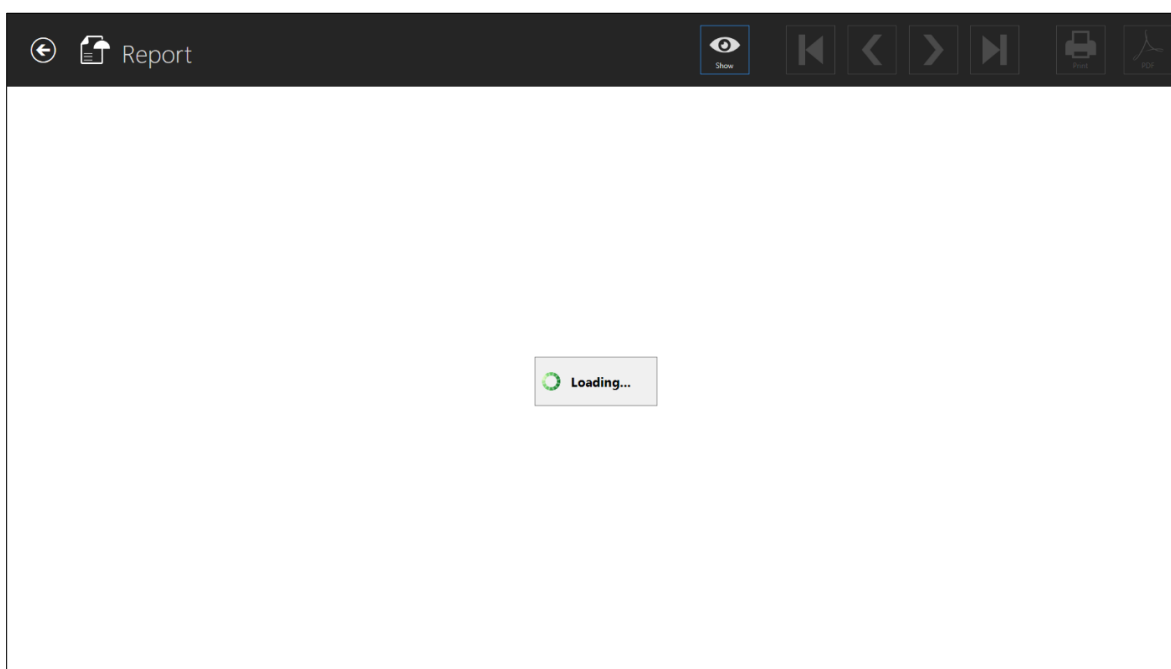


Figure 7.30 Report loading view

The Report may take a while to load.

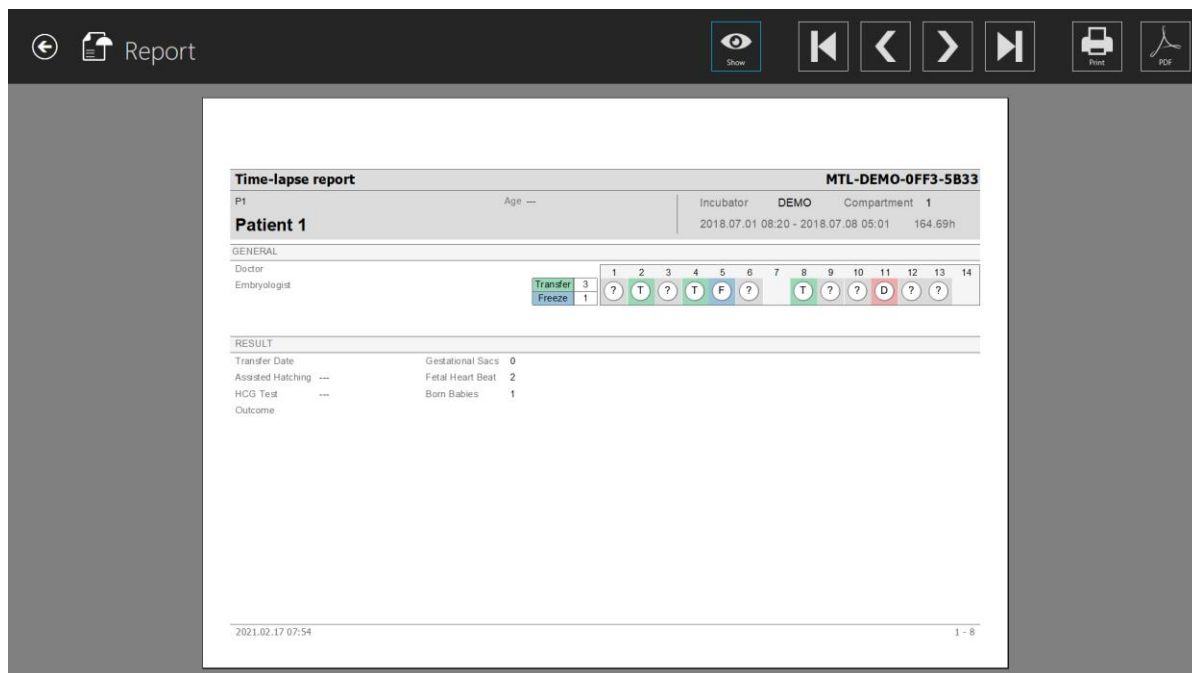


Figure 7.31 Time-lapse report view (general page)

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

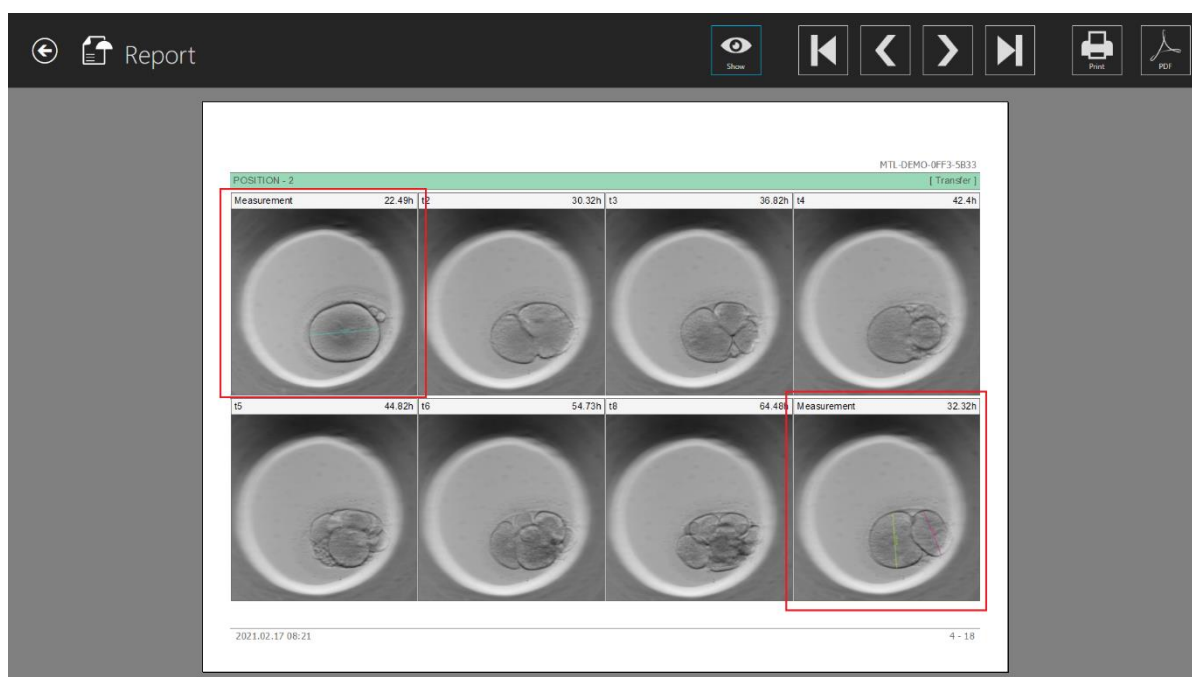


Figure 7.32 Images with measurement in a generated time-lapse report

In the picture below are all annotation overview matrices.

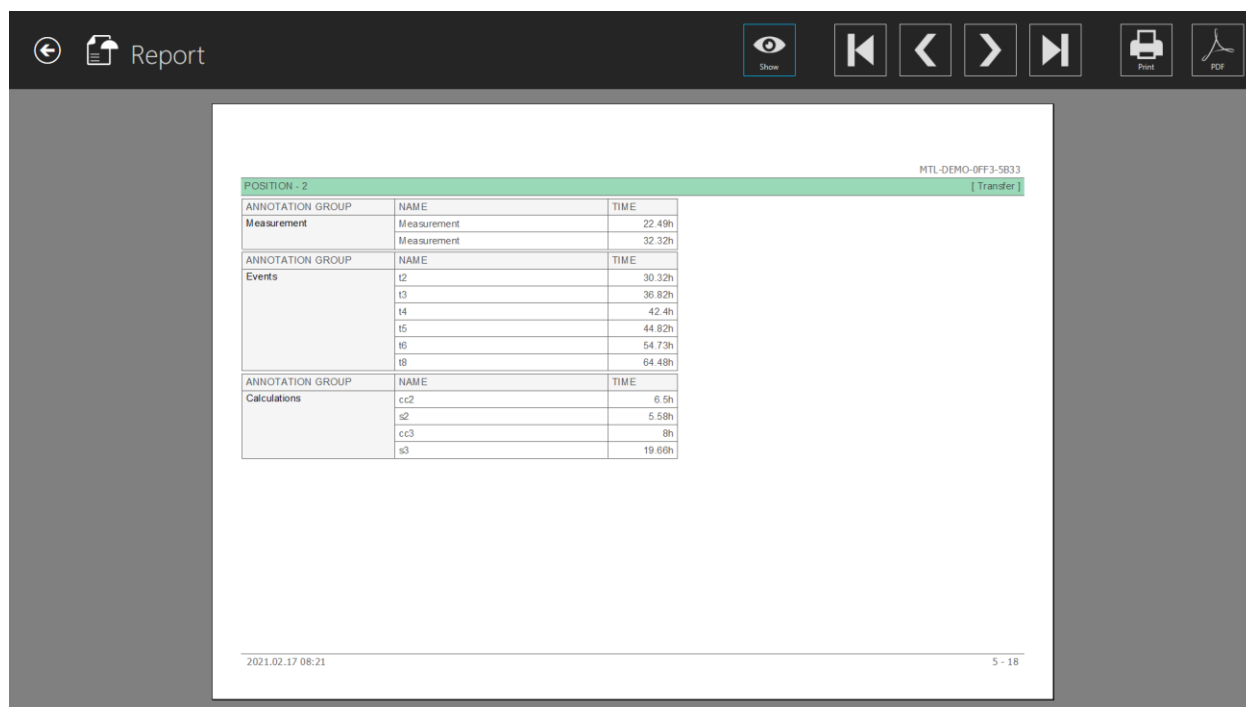


Figure 7.33 Time-lapse report view (annotations)



All new additional information (i.e., outcomes, gestational sacs, etc.) is also included in the time-lapse Report (Fig. 7.30).

7.3.3.9 Summary view function

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

In the first view that opens up, the well numbers from 1 to 14 are shown in the top art lines, top to bottom. In an example, well number 1 is first. In a horizontal line, the annotations made for well number 1 are shown. Under well number 1 is number 2 and the annotations for that well in the horizontal line, and so forth.

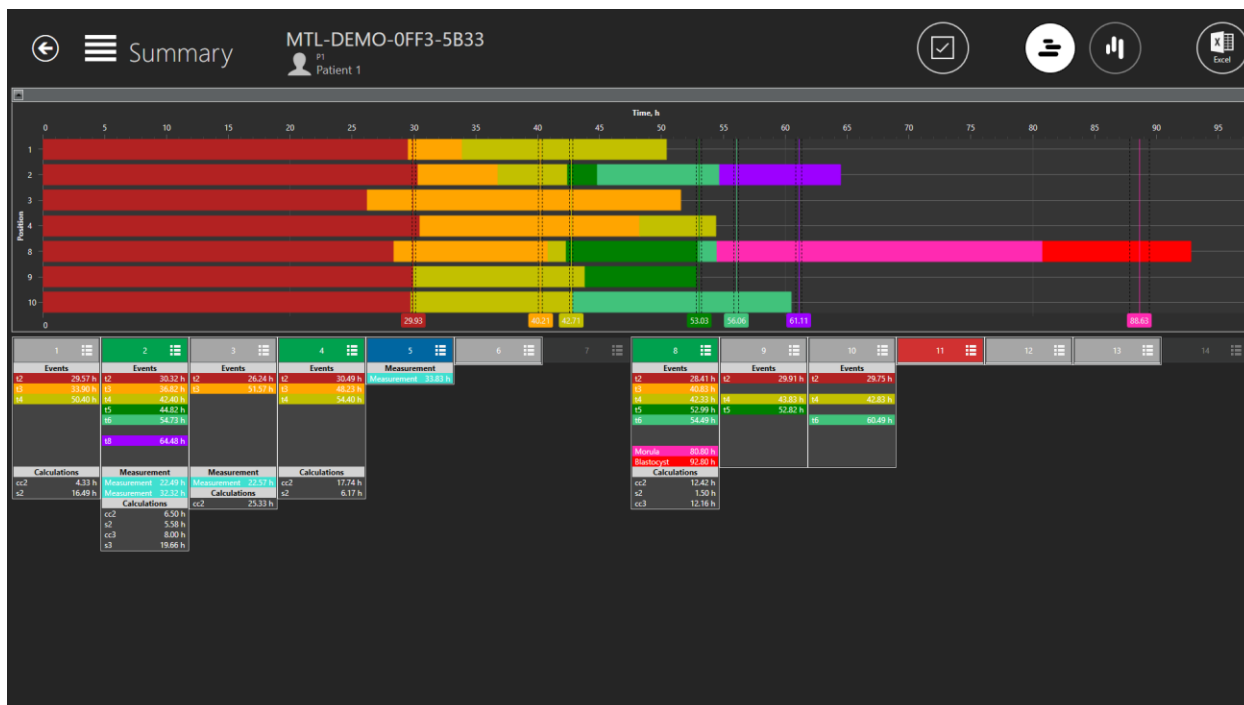


Figure 7.34 All selected dish positions in a summary view

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

The wells numbers are listed horizontally under the graphical lines and the events annotated are shown in text vertically under each.

There is a possibility of selecting/deselecting all dish positions by clicking on a checkmark in a summary view.

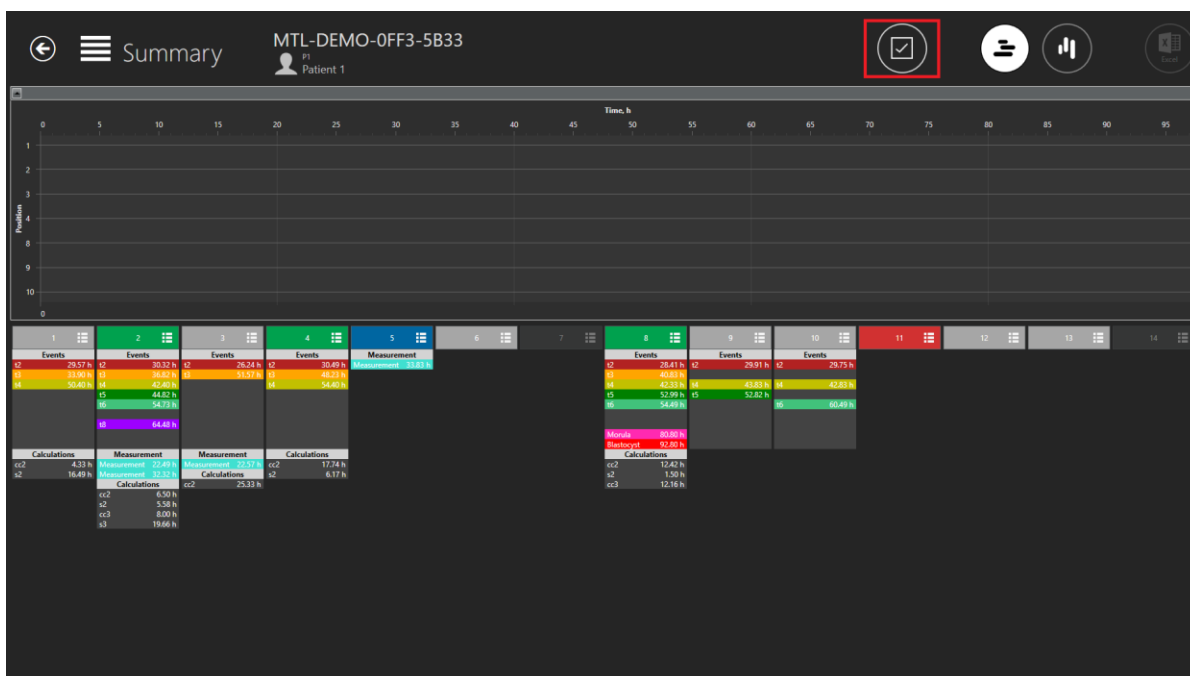


Figure 7.35 All deselected dish positions in a summary view

Showing the well on the graphical line can be toggled “ON/OFF” by pressing anywhere on the listed annotation information. A white border is shown on the wells that are “ON” and when it is toggled “OFF”, the line disappears.

The user can select the desired dish positions by clicking on them.

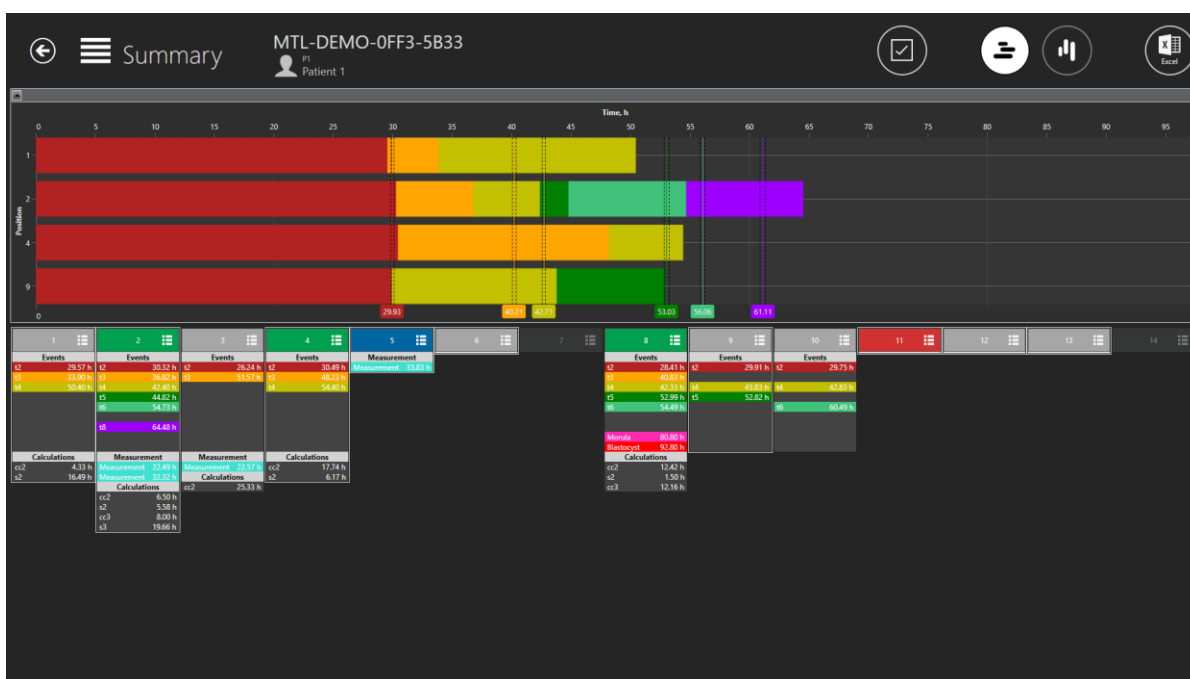


Figure 7.36 Selected dish positions in a summary view

Events annotations are in alignment for comparison, but measurements and calculations are listed normally.

1	2	3	4	5	6
Events	Events	Events	Events	Measurement	
t2 29.57 h	t2 30.32 h	t2 26.24 h	t2 30.49 h	Measurement 33.83 h	
t3 33.90 h	t3 36.82 h	t3 51.57 h	t3 48.23 h		
t4 50.40 h	t4 42.40 h		t4 54.40 h		
	t5 44.82 h				
	t6 54.73 h				
	t8 64.48 h				
Calculations	Measurement	Measurement	Calculations		
cc2 4.33 h	Measurement 22.49 h	Measurement 22.57 h	cc2 17.74 h		
s2 16.49 h	Measurement 32.32 h	Calculations	s2 6.17 h		
	Calculations	cc2 25.33 h			
	cc2 6.50 h				
	s2 5.58 h				
	cc3 8.00 h				
	s3 19.66 h				

Figure 7.37 Event annotation are in alignment

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

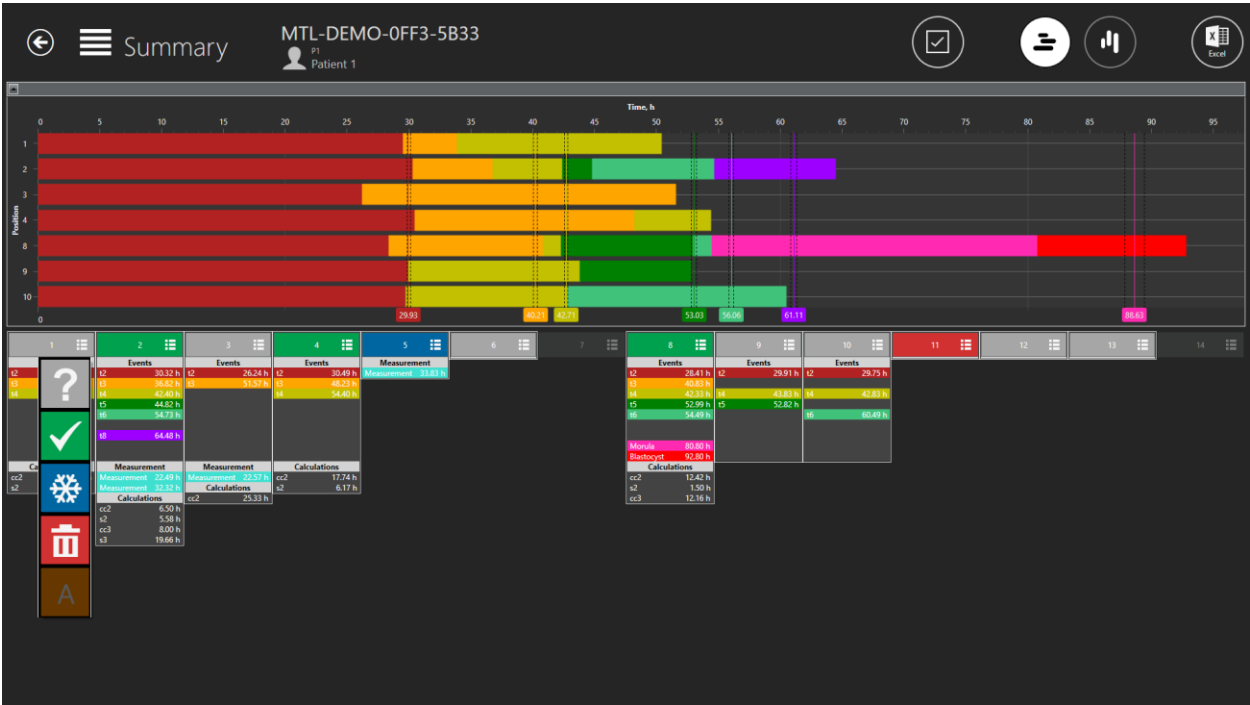


Figure 7.38 Dish status selection option in a vertical summary view

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.

The second summary view lists the events horizontally 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.

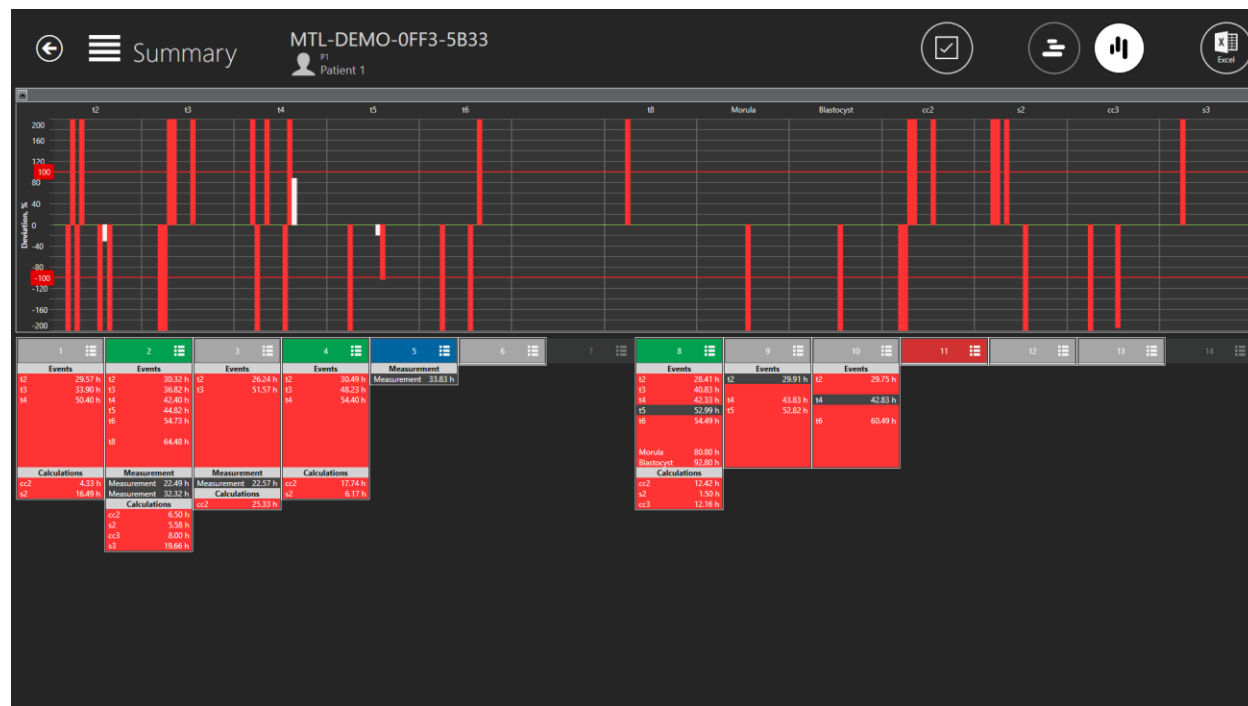


Figure 7.39 Horizontal summary view

Again, the showing the well on the graphical line can be toggled “ON/OFF” by pressing anywhere on the listed annotation information. A white border is shown on the wells that are “ON” and when it is toggled “OFF”, the line disappears.

The line is 200% off in the graph, which means that the ideal time deviation is more than 200%.

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

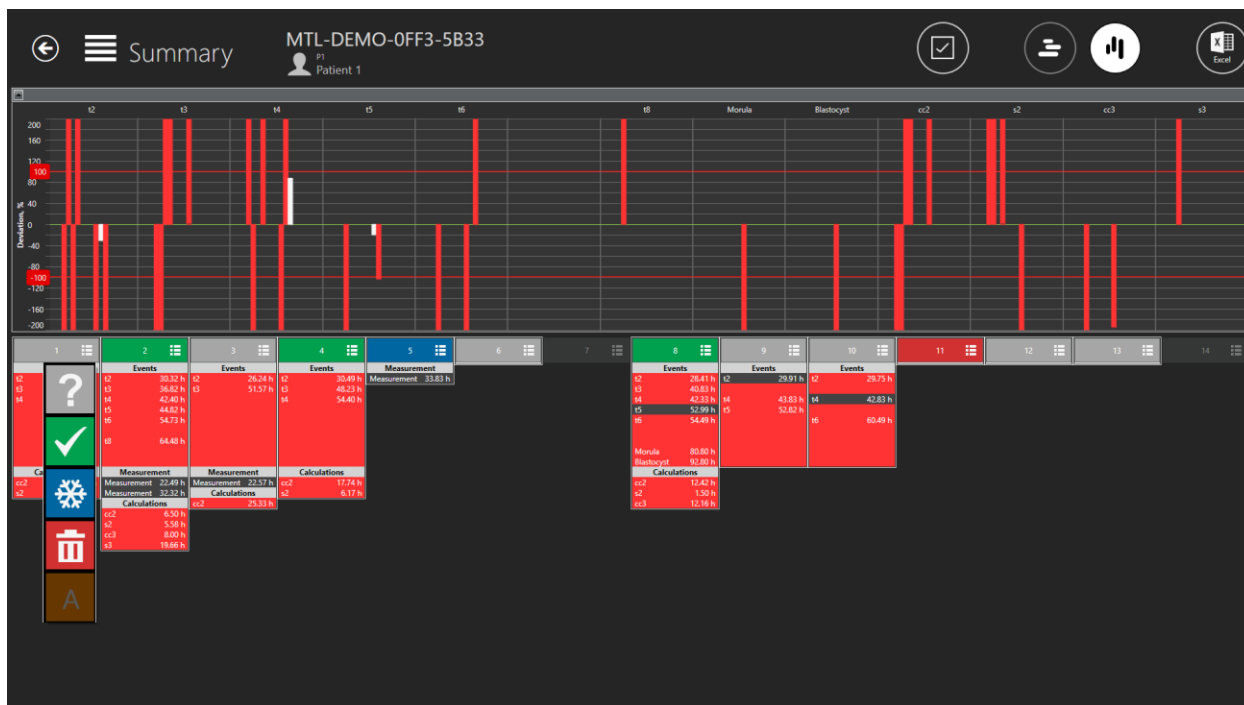


Figure 7.40 Dish status selection option in a horizontal summary view

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.

7.4 Patients

7.4.1 Patient list view

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

Patients				
Last Outcome : All		Patient name or code		
Code #	Name	Diagnosis	Last Outcome	Created
P2	Patient 2			2021-02-11 14:37
P1	Patient 1		test	2015-05-10 12:00

Figure 7.41 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 7.42 Last outcome filtration

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

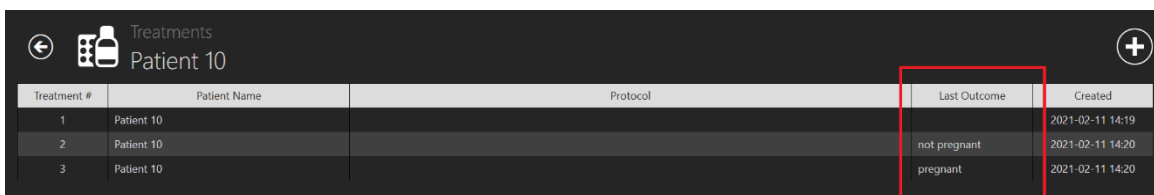


Figure 7.43 Patient treatment outcome filtration

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.

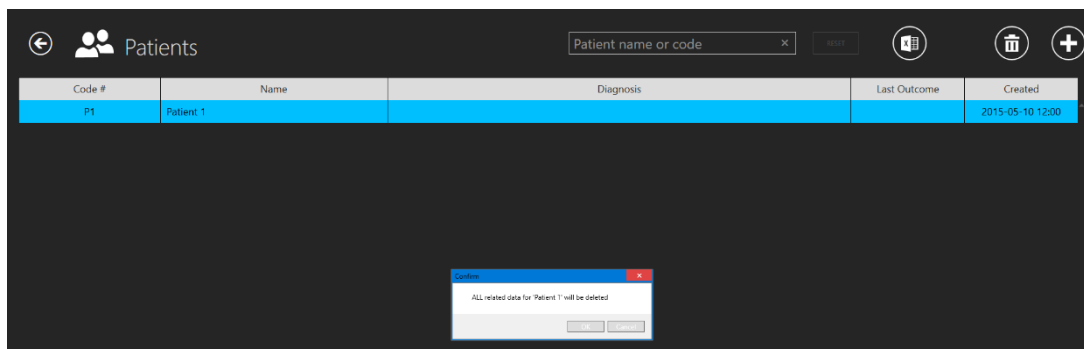


Figure 7.44 Confirmation window that all selected patient's data will be deleted

There will be a big “Time-lapses” button to the right under the particular patient.

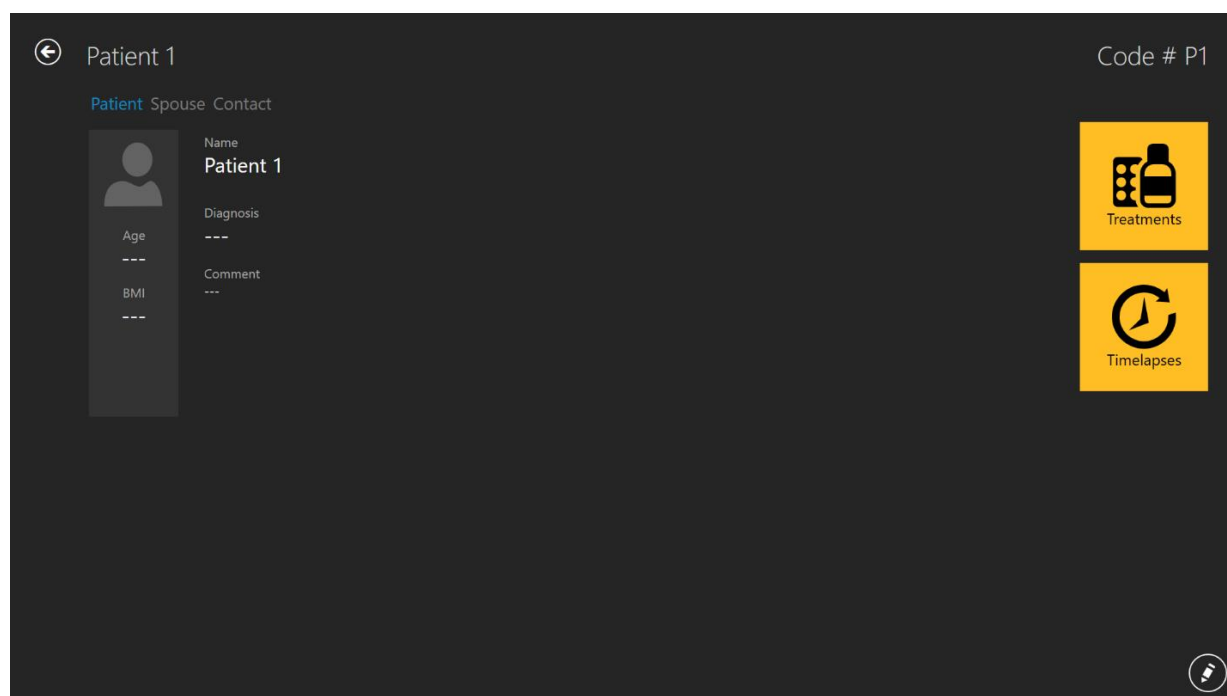


Figure 7.45 Selected patient view

Pressing on the “Time-lapses” button will open the time-lapses 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-0FCS-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 7.46 Selected patient time-lapses view

7.4.2 Patient view

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

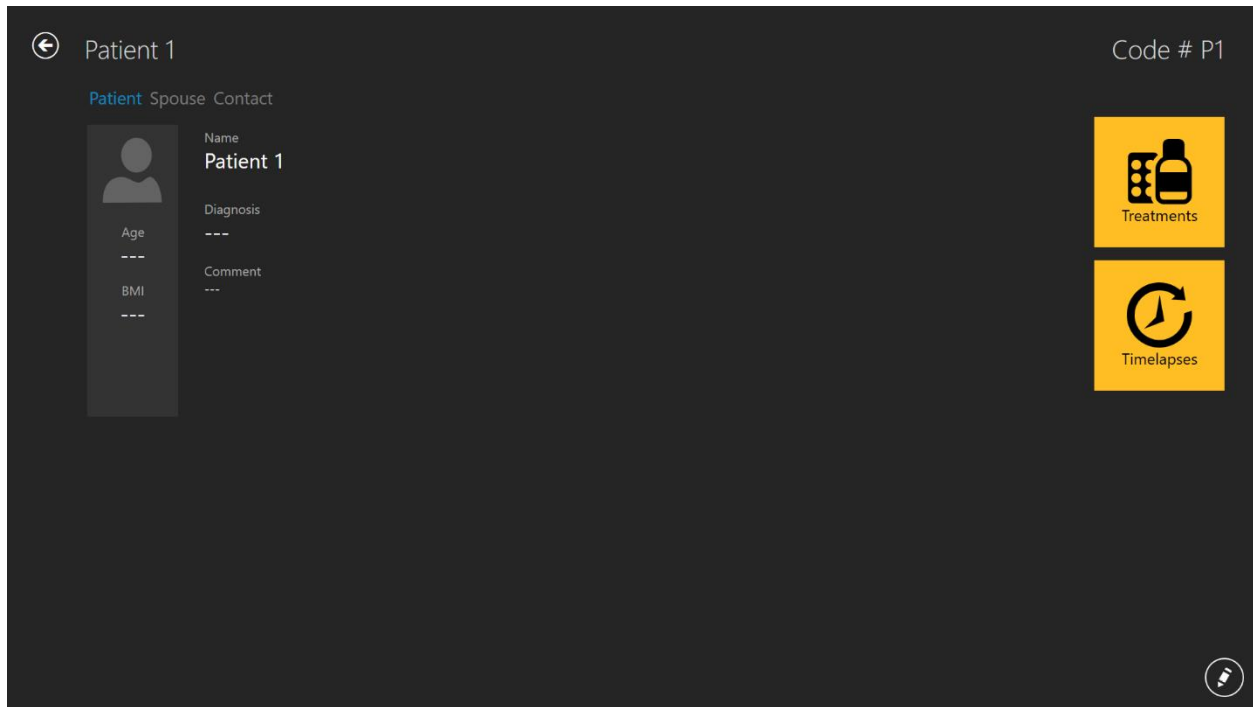


Figure 7.47 Selected patient view

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:

← + Code #

Patient Spouse Contact

Code #

Name

Birth Date Age

Select a date ---

Diagnosis

Comment

Save

Figure 7.48 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.

The screenshot shows a patient information form with a dark background. At the top left, there is a back arrow and a plus sign. At the top right, it says "Code #". Below this, there are tabs for "Patient", "Spouse", and "Contact", with "Patient" being the active tab. The form contains several input fields: "Code #", "Name", "Birth Date" (with a "Select a date" button), and "Age" (with a "---" button). A calendar for January 2021 is open, showing dates from 27 to 31. The date 19 is highlighted. At the bottom right, there is a save icon.

Figure 7.49 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.

The screenshot shows the same patient information form as Figure 7.49, but with a red warning message "The Name field is required." next to the "Name" input field. The "Birth Date" and "Age" fields are still present. Below the "Name" field, there are fields for "Diagnosis" and "Comment". At the bottom, there is a "Correct errors" button and a save icon.

Figure 7.50 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 7.51 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 7.52 Contact information window

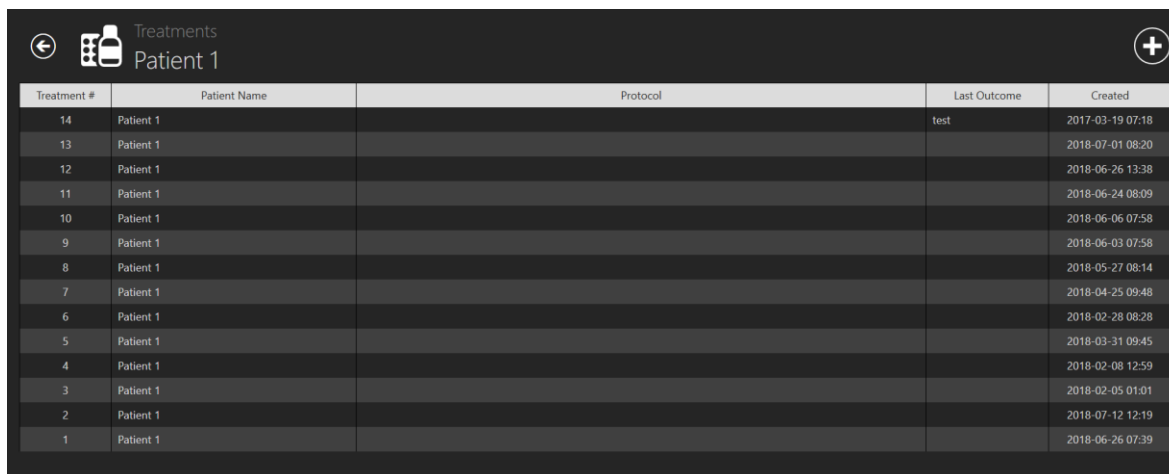
Various phone numbers, e-mail and addresses can be entered. The save button in the lower right corner stores the information.

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 read section 7.4.2).

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.

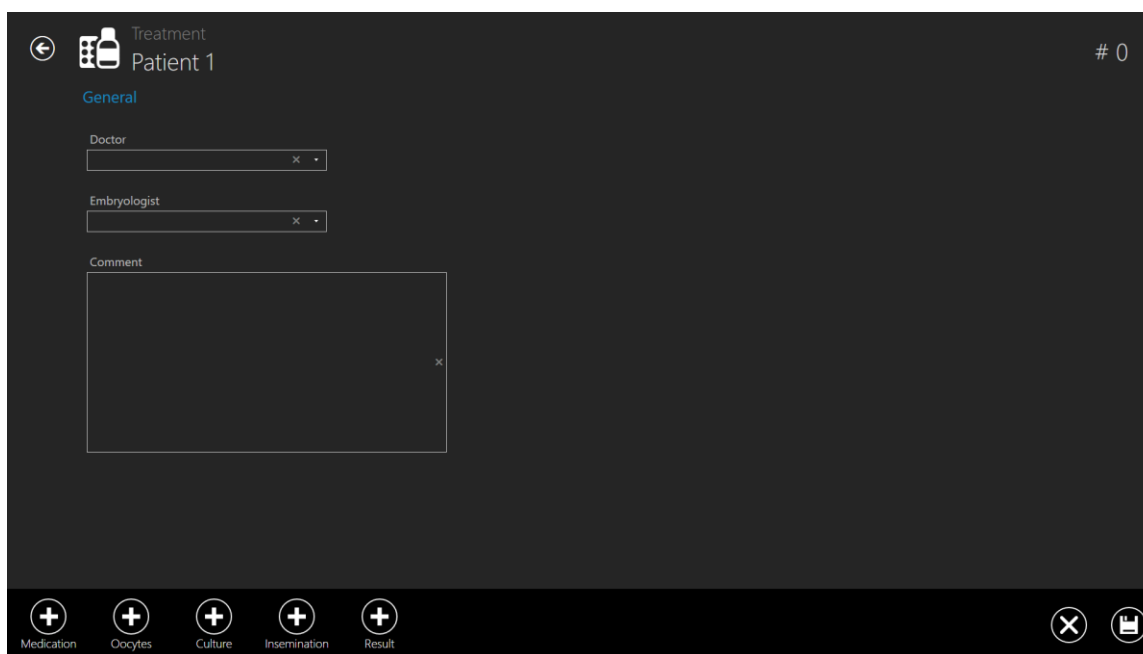


The screenshot shows a mobile application interface for viewing treatments for a specific patient. At the top, there is a header bar with a back arrow, a syringe icon, the text 'Treatments Patient 1', and a plus icon. Below the header is a table with five columns: 'Treatment #', 'Patient Name', 'Protocol', 'Last Outcome', and 'Created'. The table contains 14 rows of data, with treatment numbers ranging from 1 to 14. The 'Patient Name' column for all rows is 'Patient 1'. The 'Protocol' column is empty for all rows. The 'Last Outcome' column has the value 'test' for treatment #14 and is empty for others. The 'Created' column shows various timestamps. The table has alternating light and dark gray rows.

Treatment #	Patient Name	Protocol	Last Outcome	Created
14	Patient 1		test	2017-03-19 07:18
13	Patient 1			2018-07-01 08:20
12	Patient 1			2018-06-26 13:38
11	Patient 1			2018-06-24 08:09
10	Patient 1			2018-06-06 07:58
9	Patient 1			2018-06-03 07:58
8	Patient 1			2018-05-27 08:14
7	Patient 1			2018-04-25 09:48
6	Patient 1			2018-02-28 08:28
5	Patient 1			2018-03-31 09:45
4	Patient 1			2018-02-08 12:59
3	Patient 1			2018-02-05 01:01
2	Patient 1			2018-07-12 12:19
1	Patient 1			2018-06-26 07:39

Figure 7.53 Selected patient treatment view

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



The screenshot shows a mobile application interface for adding a new treatment. At the top, there is a header bar with a back arrow, a syringe icon, the text 'Treatment Patient 1', and a '# 0' indicator. Below the header is a form with three sections: 'General', 'Doctor', and 'Embryologist'. The 'General' section has a 'Comment' text area. The 'Doctor' and 'Embryologist' sections have dropdown menus. At the bottom, there is a navigation bar with five icons: a plus icon, a plus icon, a plus icon, a plus icon, and a plus icon, labeled 'Medication', 'Oocytes', 'Culture', 'Insemination', and 'Result'. There are also close and save icons on the right side of the bottom bar.

General

Doctor

Embryologist

Comment

Medication Oocytes Culture Insemination Result

Figure 7.54 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 are optional information. Save if the information is entered.

The first “Plus” button will bring up the “Medication” section.

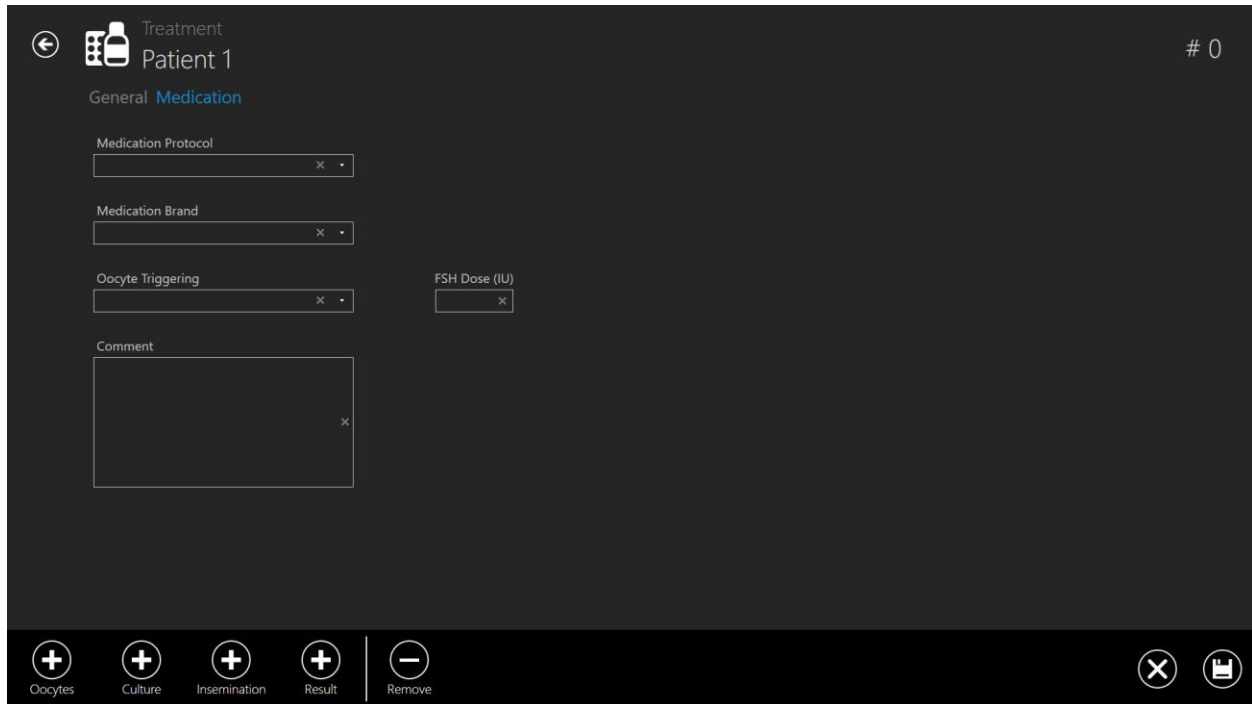
The screenshot shows a software interface for patient treatment. At the top, there's a header with a back arrow, a syringe icon, the text 'Treatment Patient 1', and a '# 0' indicator. Below the header, there are two tabs: 'General' and 'Medication', with 'Medication' being the active tab. The 'Medication' section contains several input fields: 'Medication Protocol' (a dropdown menu), 'Medication Brand' (a dropdown menu), 'Oocyte Triggering' (a dropdown menu), 'FSH Dose (IU)' (a text input field), and a 'Comment' (a large text area). At the bottom of the screen, there is a navigation bar with five buttons: 'Oocytes', 'Culture', 'Insemination', 'Result', and 'Remove'. The 'Oocytes' button is highlighted with a plus sign. To the right of these buttons are two more icons: a close button (X) and a save button (floppy disk).

Figure 7.55 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 since the view is currently open.

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

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

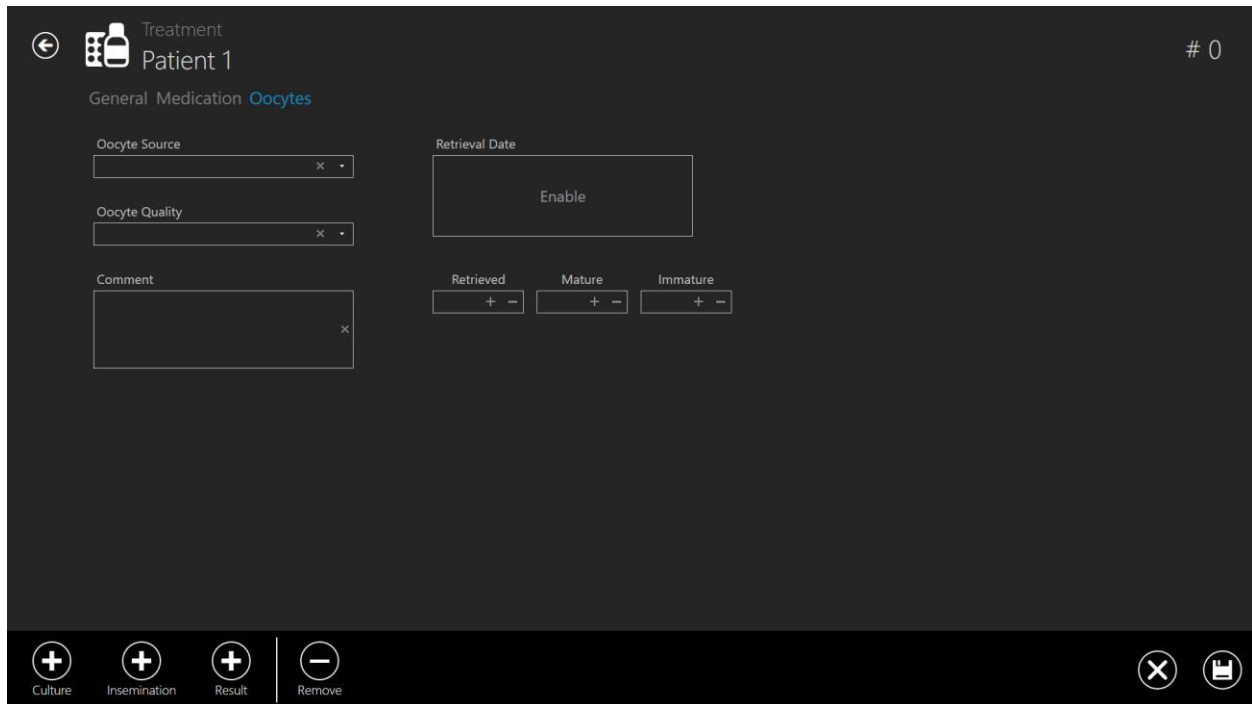
The screenshot shows a software interface for patient treatment. At the top, there's a header with a back arrow, a syringe icon, and the text 'Treatment Patient 1'. On the right, it says '# 0'. Below the header, there are three tabs: 'General', 'Medication', and 'Oocytes' (which is highlighted in blue). The 'Oocytes' section contains several input fields: 'Oocyte Source' and 'Oocyte Quality' are dropdown menus; 'Retrieval Date' is a date picker with an 'Enable' button; 'Comment' is a text area; and there are three sets of increment/decrement buttons labeled 'Retrieved', 'Mature', and 'Immature'. At the bottom, there's a navigation bar with four buttons: 'Culture', 'Insemination', 'Result', and 'Remove' (which has a minus sign). On the far right of the bottom bar are two circular icons: one with an 'X' and one with a document icon.

Figure 7.56 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.

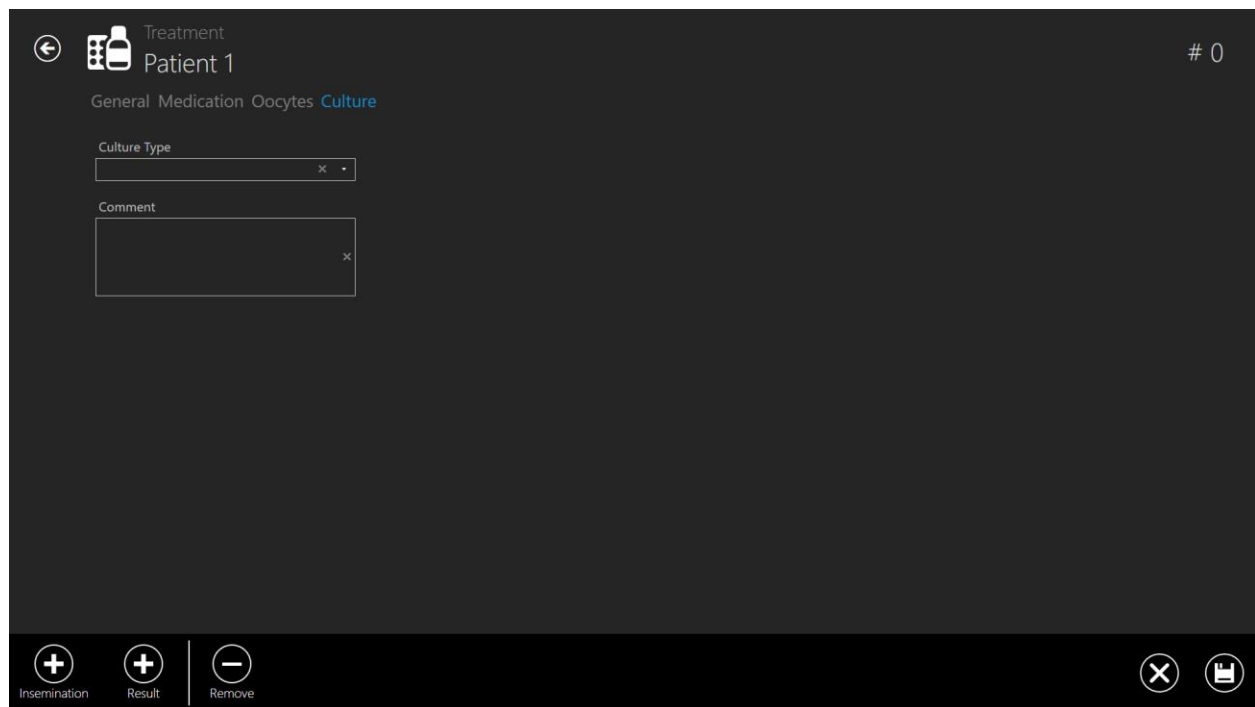


Figure 7.57 Added “Culture” section

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.

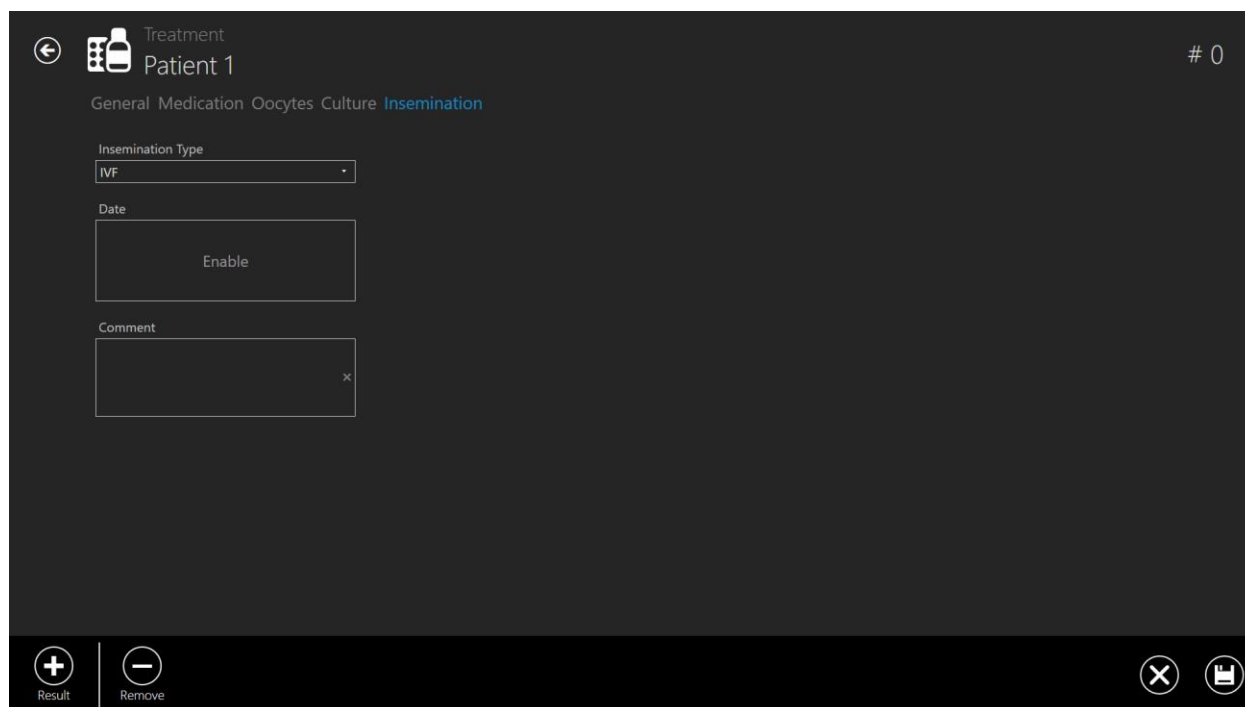

The screenshot shows a software interface for patient treatment. At the top, there's a header with a back arrow, a syringe icon, and the text 'Treatment Patient 1'. To the right is a '# 0' indicator. Below the header, there's a navigation bar with 'General', 'Medication', 'Oocytes', 'Culture', and 'Insemination' (which is highlighted in blue). The main area contains three input fields: 'Insemination Type' with a dropdown menu showing 'IVF', 'Date' with an 'Enable' button, and 'Comment' with a text area and a close icon. At the bottom, there's a dark bar with a '+ Result' button, a '- Remove' button, and two circular icons on the right: one with an 'X' and one with a document icon.

Figure 7.58 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 time-lapse 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 time-lapse 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 result section.

Figure 7.59 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.

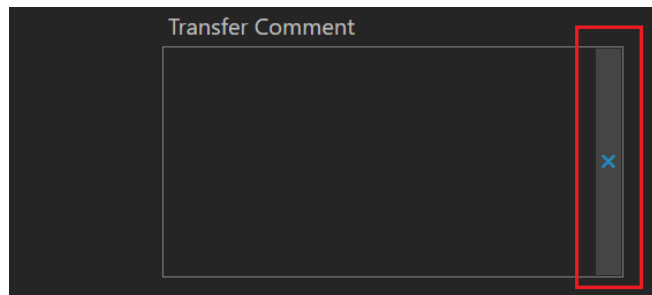


Figure 7.60 “Clear” button

7.4.4 Time-lapse creation view

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



Figure 7.61 “Add time-lapse” button under the specific patient treatment

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

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

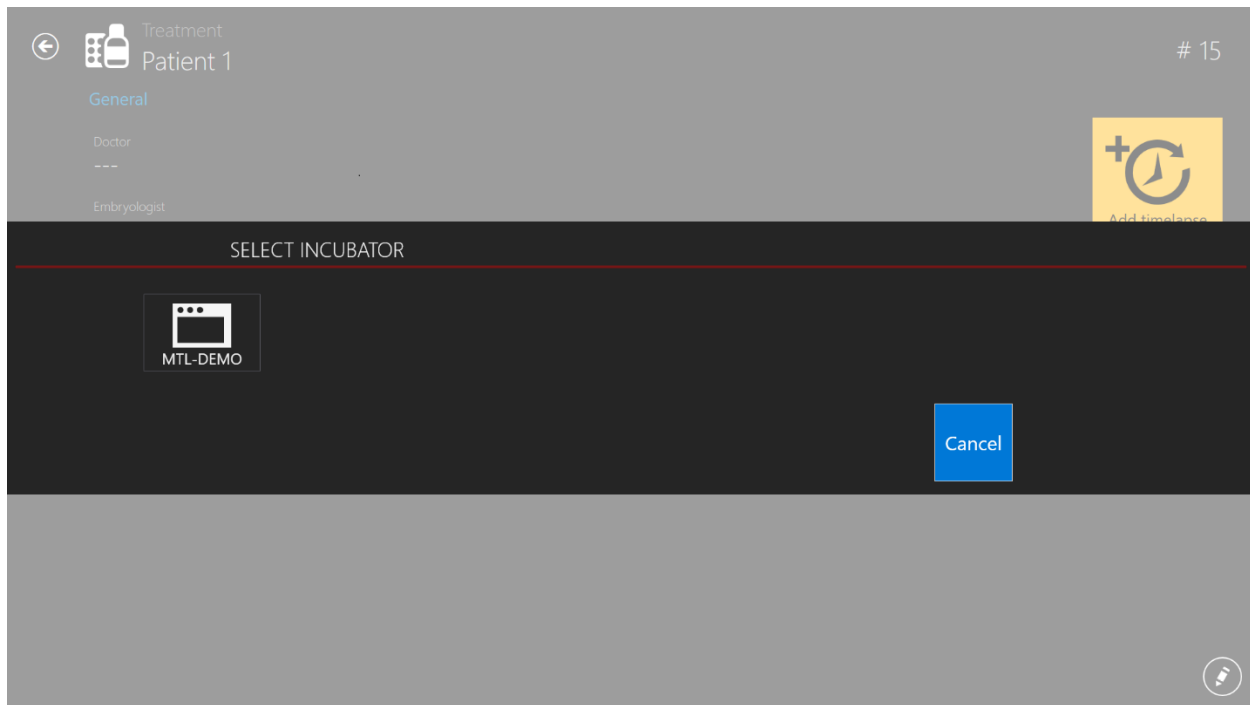



Figure 7.62 Select the device in which time-lapse is sent

 **One treatment can only have one time-lapse. If the user wants to add more time-lapses for the patient, a new treatment must be added.**

 **A time-lapse 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 time-lapse cannot be started in any other way.**

 **For enabling and disabling incubator, please read more information in the section “7.5 Incubators” below.**

If the time-lapse has been made, the treatment page will look like the below, and by pressing the “Time-lapse” button, Time-lapse view will be shown:



Figure 7.63 Treatment view when the time-lapse has been made

By pressing the “Time-lapse” button, the Time-lapse view will be shown.

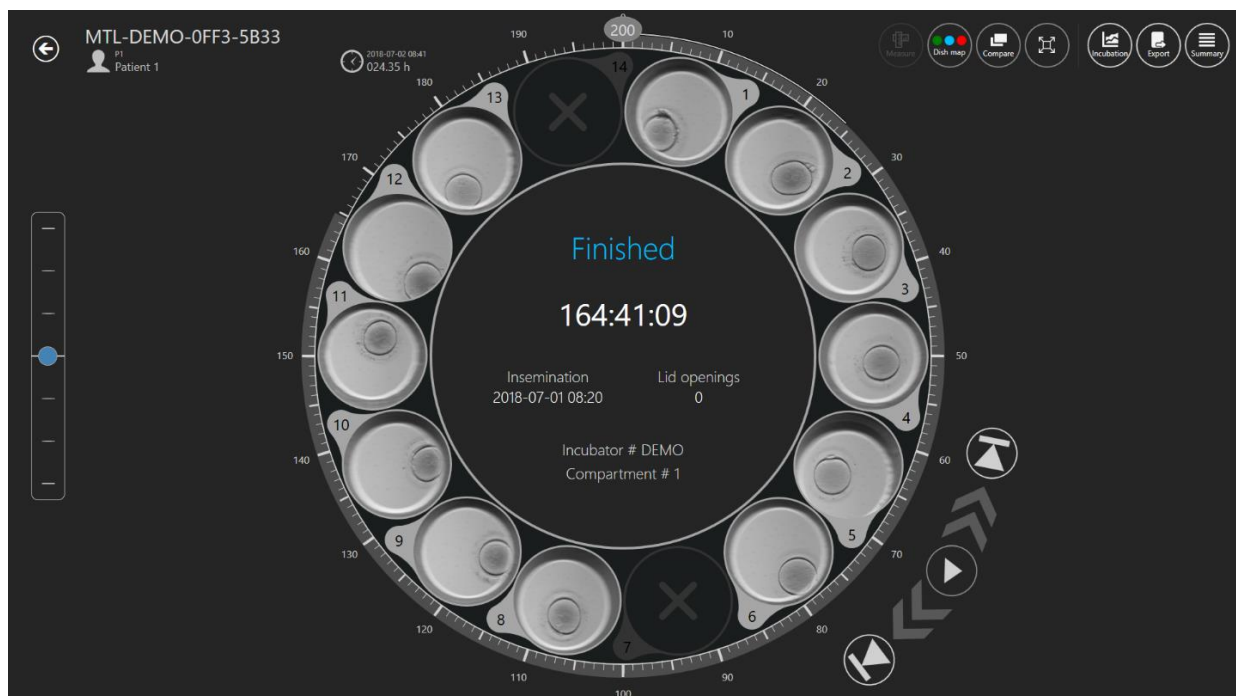


Figure 7.64 The time-lapse view of a specific patient

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 7.65 “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 time-lapse.



Figure 7.66 “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 compartment temperature incubation data is shown.

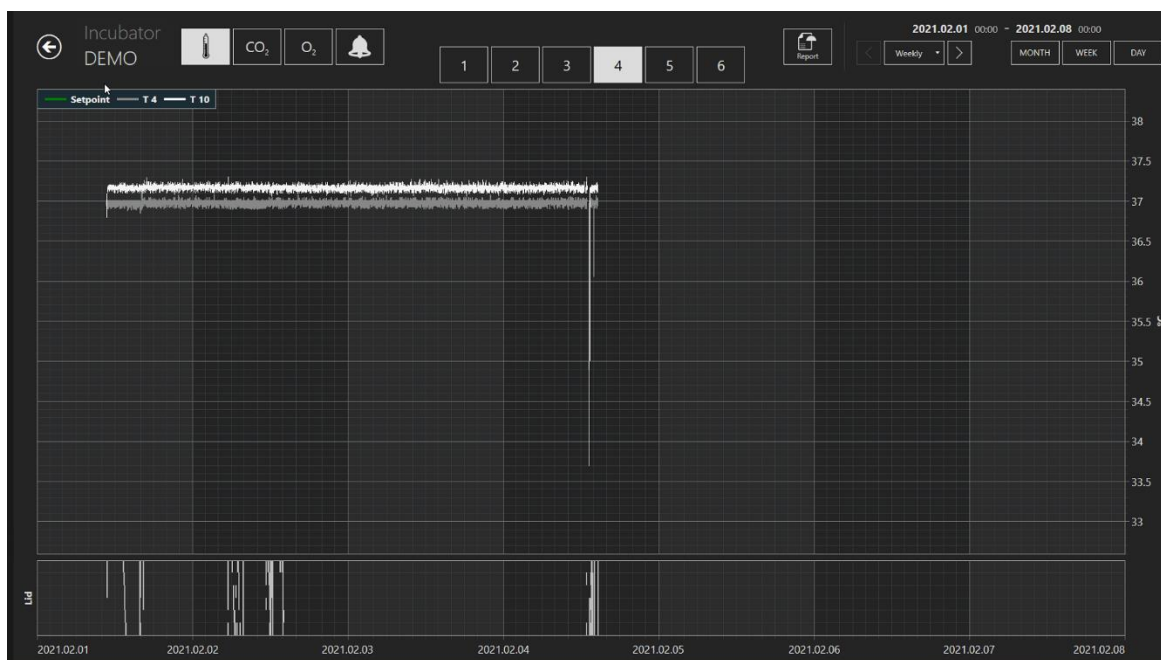


Figure 7.67 “DEMO” incubator temperature incubation data log view

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. The month is listed from the 1st month that MIRI® TL starts working.

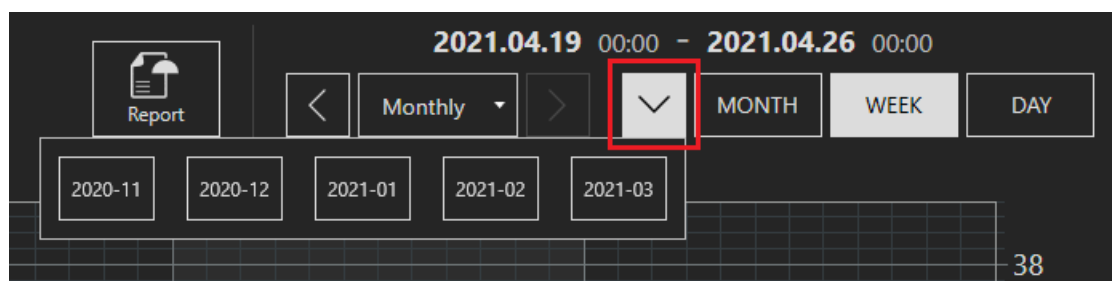


Figure 7.68 Incubation data selection options

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.

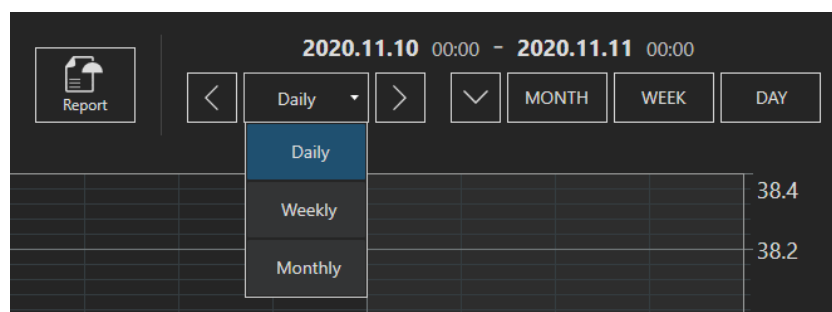


Figure 7.69 Incubation data selection options

After the selection of the desired data option, pressing the button that points left (<) and the button that points right (>), the user can 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 set up to unique user's preferences and needs.

When pressing the “Settings” button, it opens up the settings view, which contains “Annotations” and “Embryo States” sections.

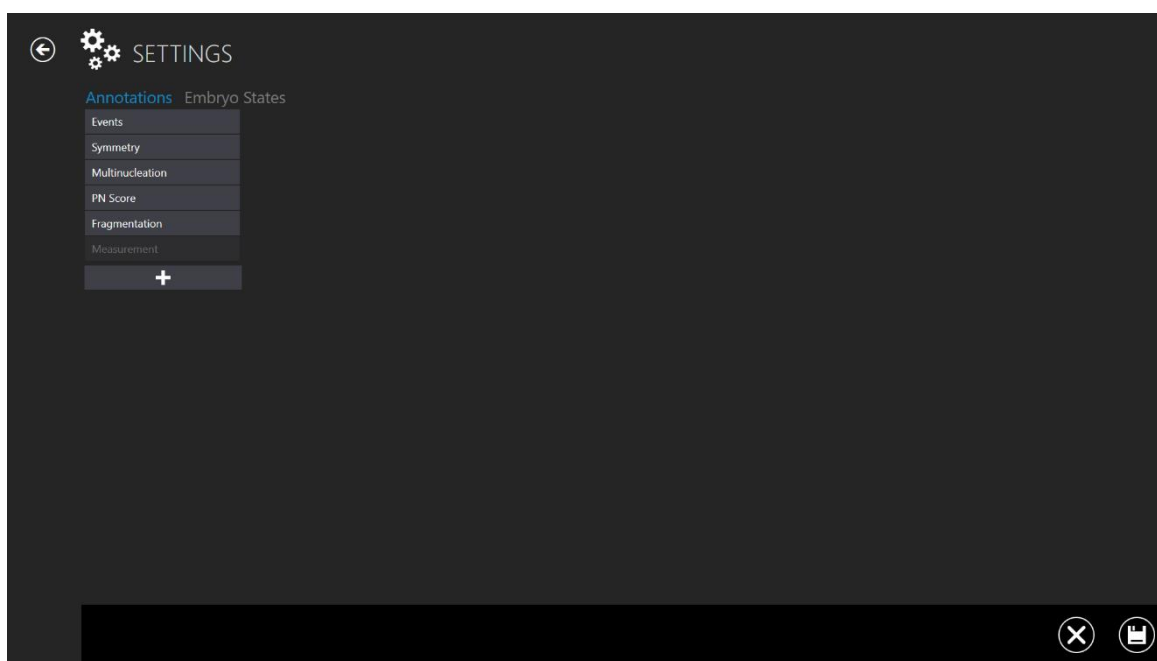


Figure 7.70 Settings view

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.

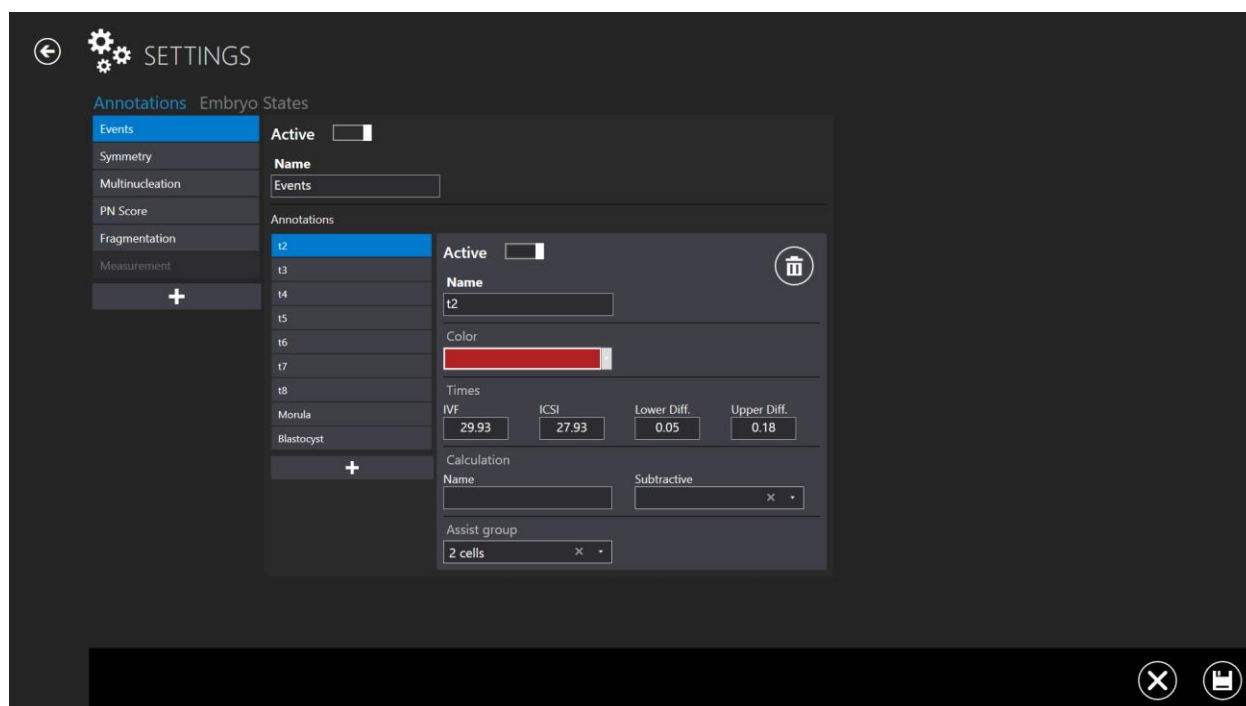


Figure 7.71 Settings – annotations – events view

Here can be seen the events that consist of annotations group. In the picture above is shown 2 (time to the two-cell stage). 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.

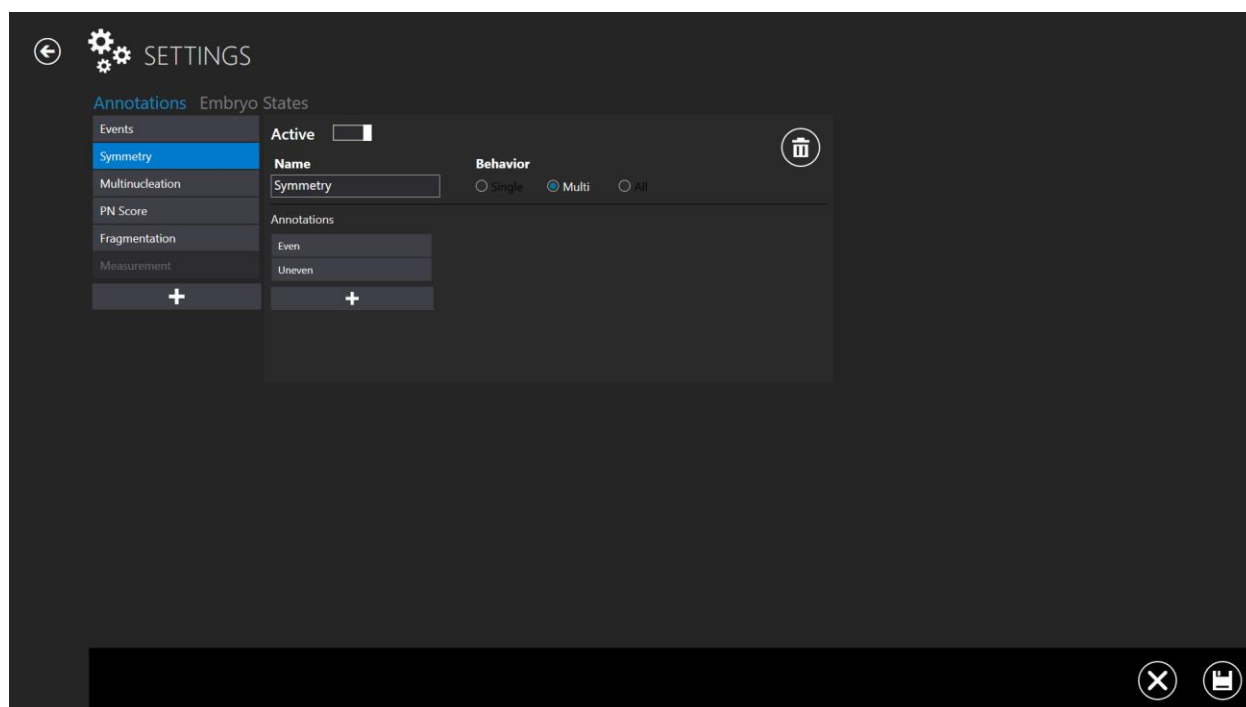


Figure 7.72 Settings – annotations – symmetry view

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 newest MIRI® TL family's multiroom IVF incubators Viewer version, a newly added “Embryo States” section allows the user to add additional embryo states.

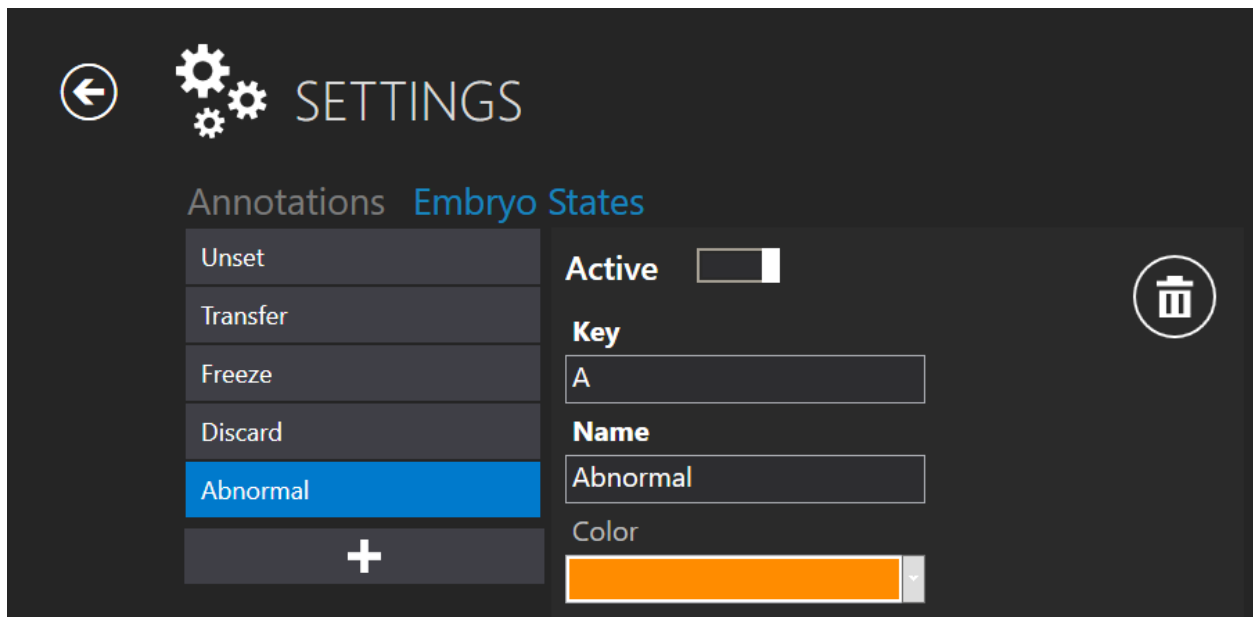


Figure 7.73 Active new embryo state

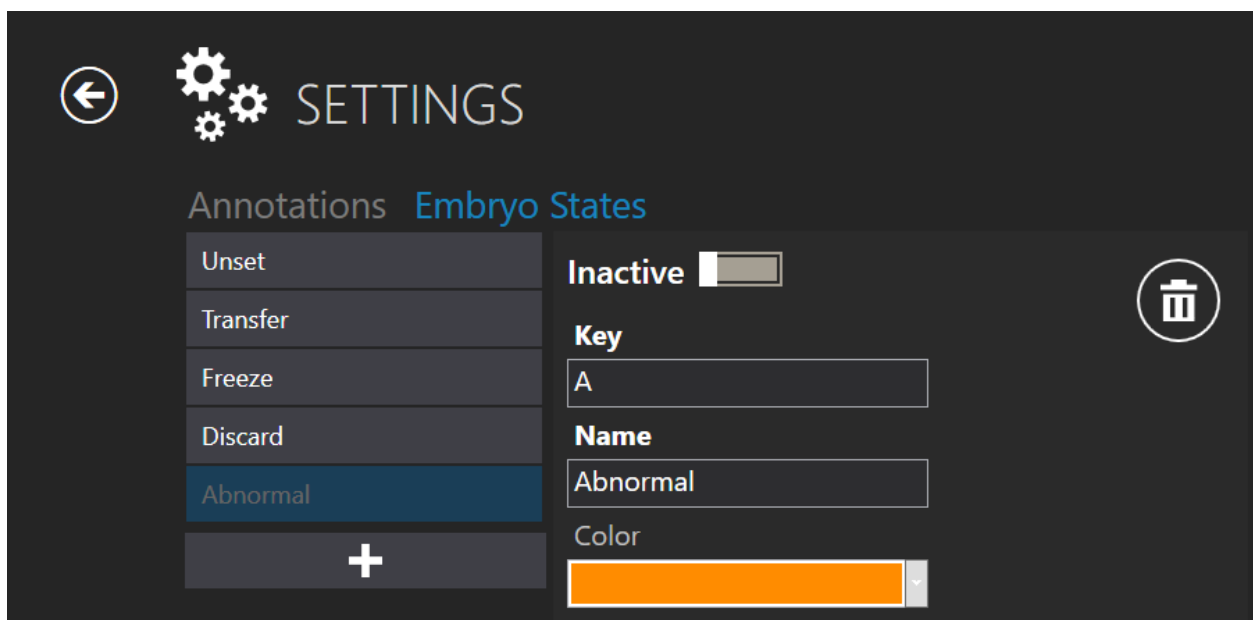


Figure 7.74 Inactive “Abnormal” embryo state

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.

8 Technical assistance

For more information, contact Esco Medical or the local representative.