ESCO MEDICAL

Life has begun

The Next Generation of Time-Lapse Systems

MIRI® TL

Time-Lapse Incubator for IVF

CERTIFIED INCUBATION

This equipment is a CE-marked device and is in conformity with the essential requirements of the Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC.

Design Excellence - Superior Quality

All the features you love about
the MIRI® Time-Lapse System.

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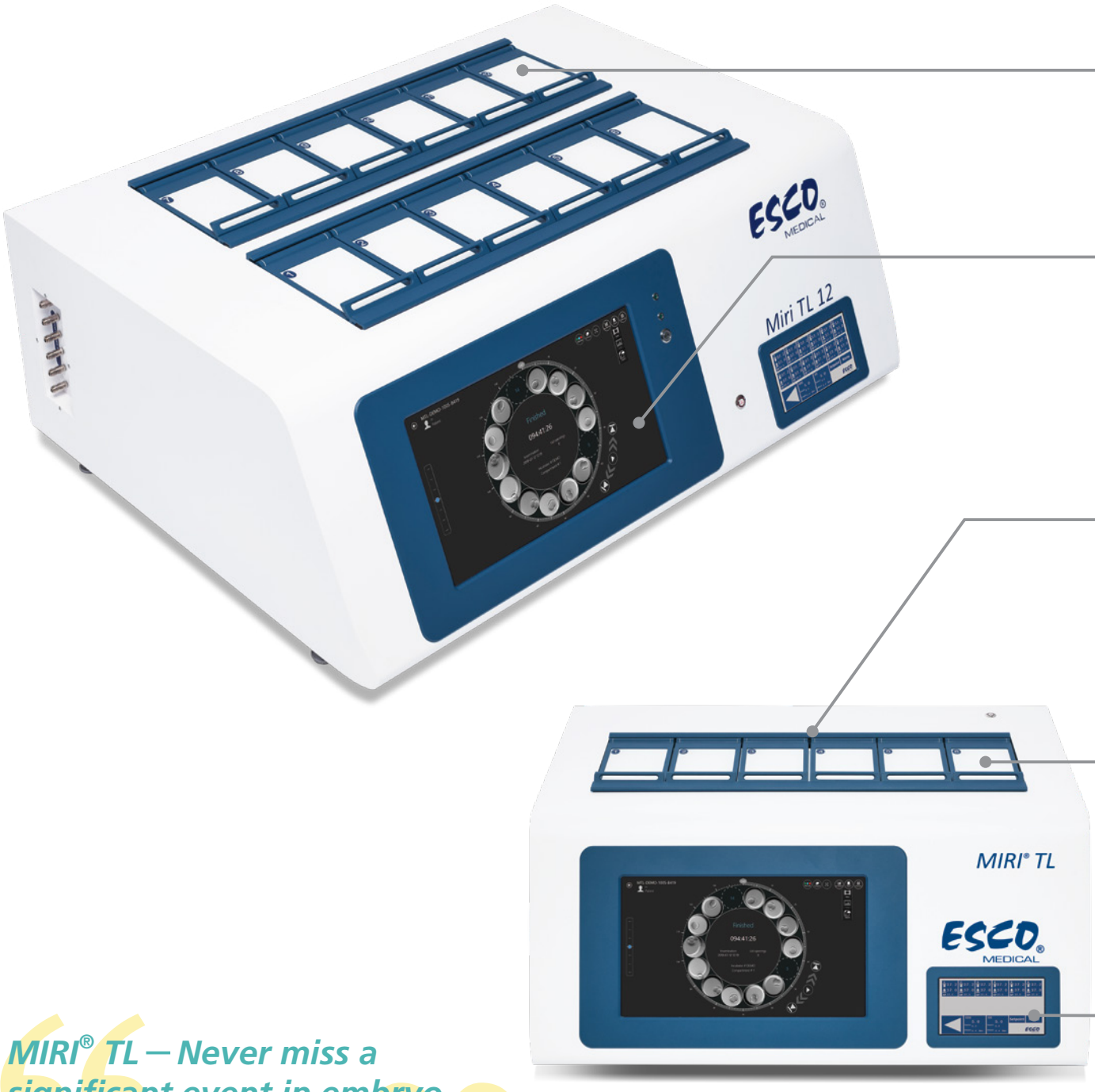
MIRI® TL

"A state of the art time-lapse incubation system for IVF"



MIRI® TL — Never miss a significant event in embryo development with the continuous monitoring system.

The MIRI® TL is a multiroom incubator with a built-in camera and microscope that allows embryologists to view the development of the embryo from fertilization until the day of transfer without any disturbances. This significantly reduces the environmental stresses on the embryo when compared to current standard incubation practices.

The technology built into the MIRI® TL allows all important events to be observed, this allows embryologists to annotate and choose the best embryos for transfer based on their morphokinetics; aiming to improve embryo traits and pregnancy rates.

FEATURES:

Heated Lid

- Prevents condensation.
- Enhances temperature regulation/recovery.
- Excellent uniformity between the top and bottom lid.

Time-Lapse Monitoring

- As images are digitally-stored, a video can be generated to enable a more objective and reliable grading of embryos.
- The Time-Lapse video enables detailed scoring of of cultured embryos, to better predict embryo development and implantation potential.

Multiroom System

The MIRI® TL6 and TL12 have multiple independent chambers with very stable environments, allowing embryologist to culture embryos from individual patients in individual chambers.

MIRI® TL6: 6 Individual chambers
MIRI® TL12: 12 Individual chambers
Gas recovery: less than three (3) minutes
Temperature recovery: less than one (1) minute

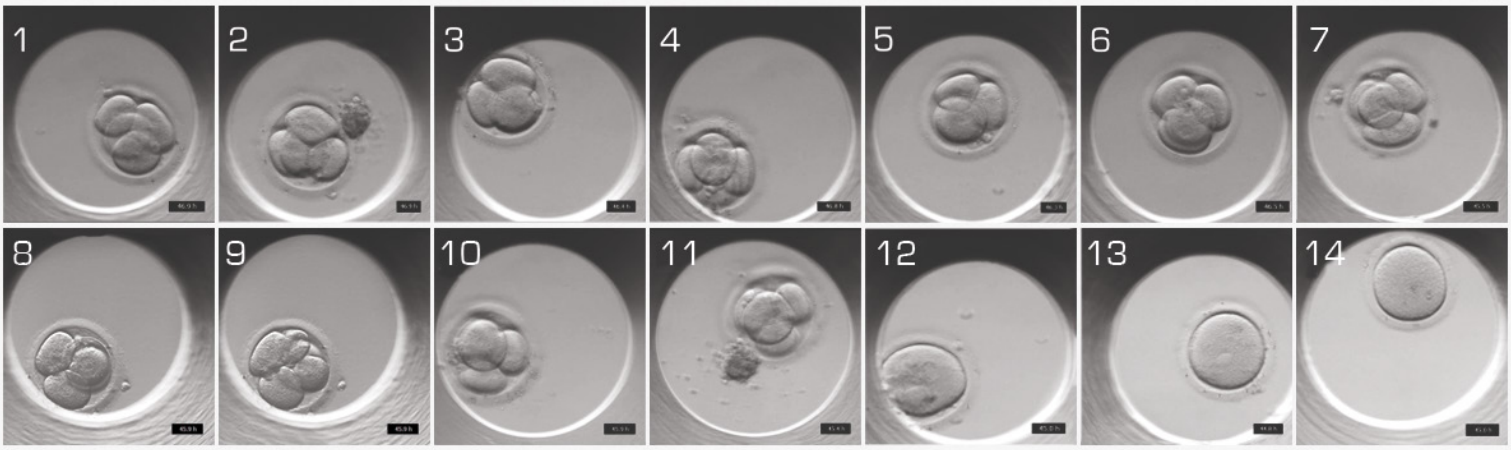
Direct Heat Transfer

- Provides superior temperature stability.
- Less than one (1) minute for temperature recovery.

2 Temperature Mode Options:
- **Single:** Uniform set points for all 6 (six) chambers
- **Multi:** Individual set points for each chamber

Touch Screen Control Panel

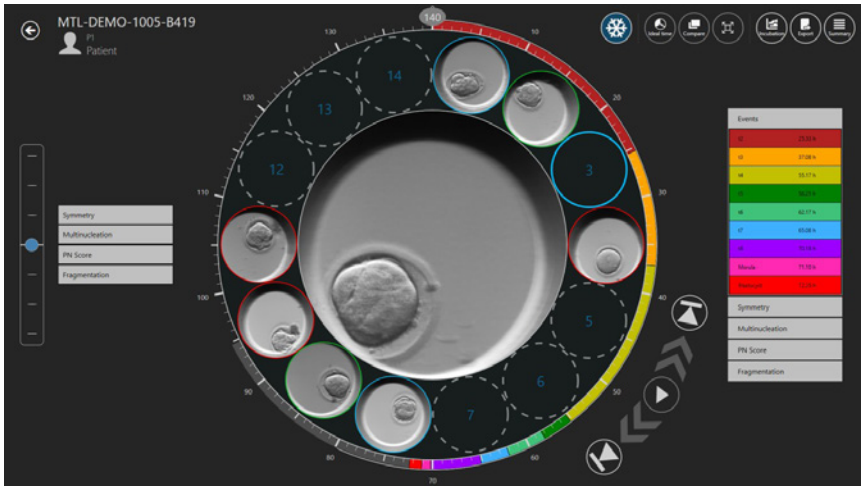
Easily change parameter settings with a reliable touch-screen display. Configuration is as simple as you need it to be.



Watch them Grow

Using a built-in camera and a microscope, the MIRI® TL can continuously capture time-lapse images of your embryo as it develops. This empowers the users with the ability to make better informed decisions in regard to the outcome of the embryos.

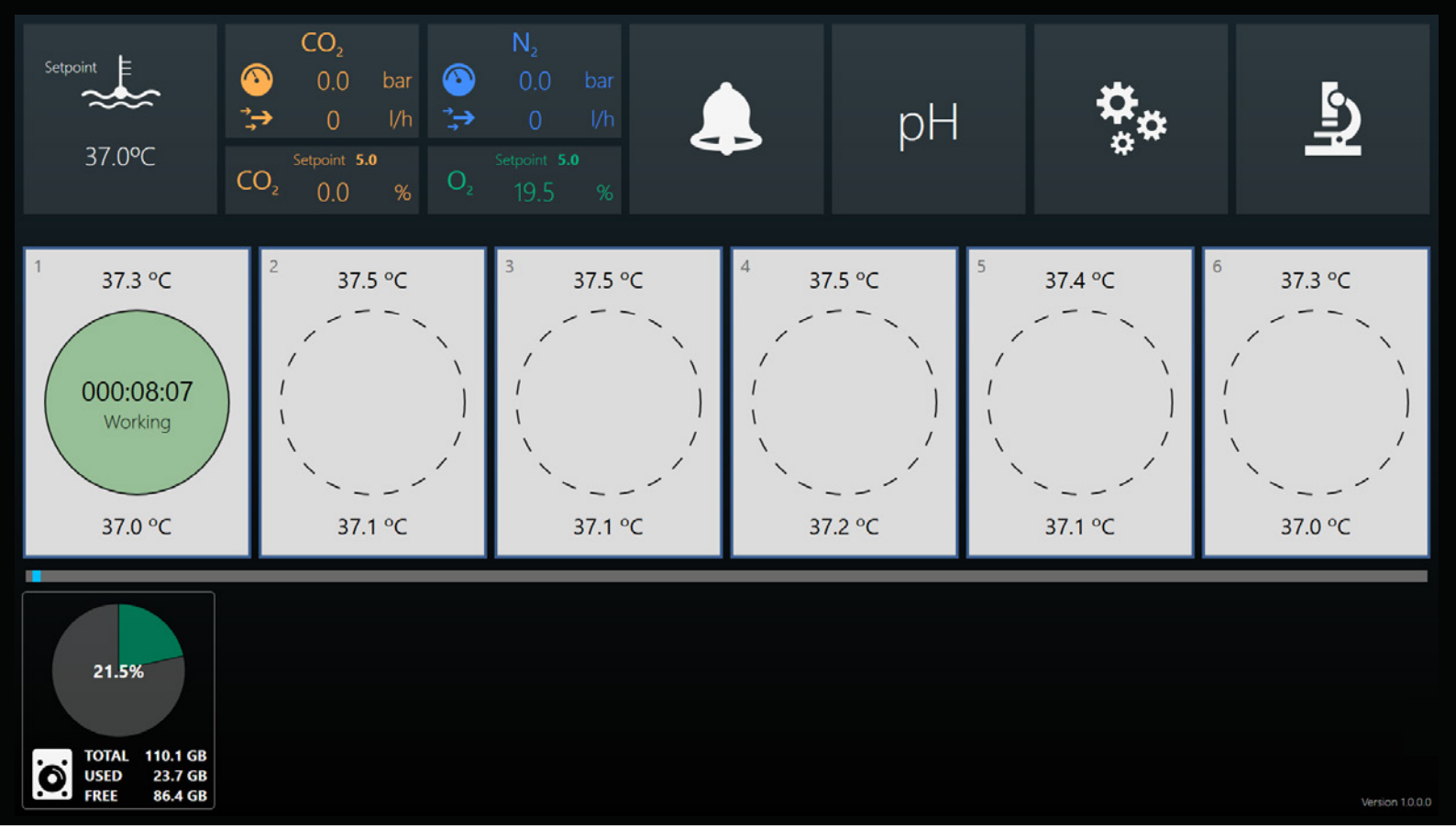
More Data under Observations, Better Selection



- By using the embryo evaluation tools on the Viewer station, only the best embryos may be selected and therefore, non-viable embryos can be eliminated from the start.
- Retrospective data analysis provides complete documentation of patient details, treatment and embryo data. This can also be used for reference, knowledge sharing and training of embryologists.

Don't miss out on crucial events

- Time-Lapse provides continuous surveillance of all embryos.
- No more missing important events:
  - ◊ actual timing of cleavages compared to ideal time
  - ◊ actual timing of morula and blastocyst stages
  - ◊ detect unusual cleavage patterns such as Direct Cleavage and Reverse Cleavage
  - ◊ synchrony of divisions
  - ◊ multinucleation
- The time-lapse session runs up to 199 hours.



Time-Lapse Embryo Recording and Monitoring

The main screen shows all chambers as each counter illustrates the duration of time-lapse recording made. At the upper right portion, snapshots of other useful information regarding the incubator such as temperature, pH measurement, CO_2 and O_2 status, and Set Points (SP) are displayed.

CultureCoin®, a culture dish, exclusively designed for the MIRI® TL

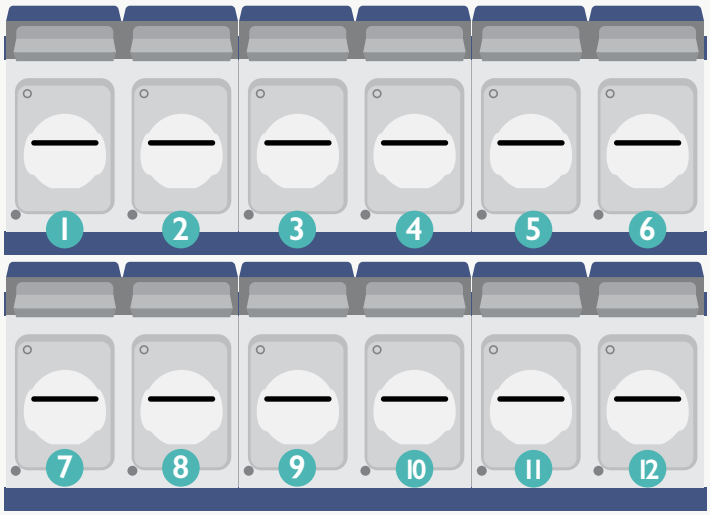
One (1) MIRI® TL chamber can hold one (1) CultureCoin®. Each dish can accommodate up to fourteen (14) embryos, each with a numbered well assignment. The MIRI® TL6 can hold up to 84 embryos, and the MIRI® TL12 up to 168 embryos.

Key Features

- Each embryo is cultured in its own stable environment.
- Ergonomic design for easy, safe, and secure handling of embryos.
- Independent well for pH measurements.
- Oxygen plasma treated surface for the effective prevention of bubble formation.
- Gamma-sterilized.

Superior Incubation Environment

In MIRI® TL, separate chambers have been designed to prevent cross-contamination during the incubation process. The independent temperature regulation ensures optimal embryo developmental conditions. This significantly reduces disturbance and minimizes stressful factors that may be introduced when taking the dishes out of the incubator.

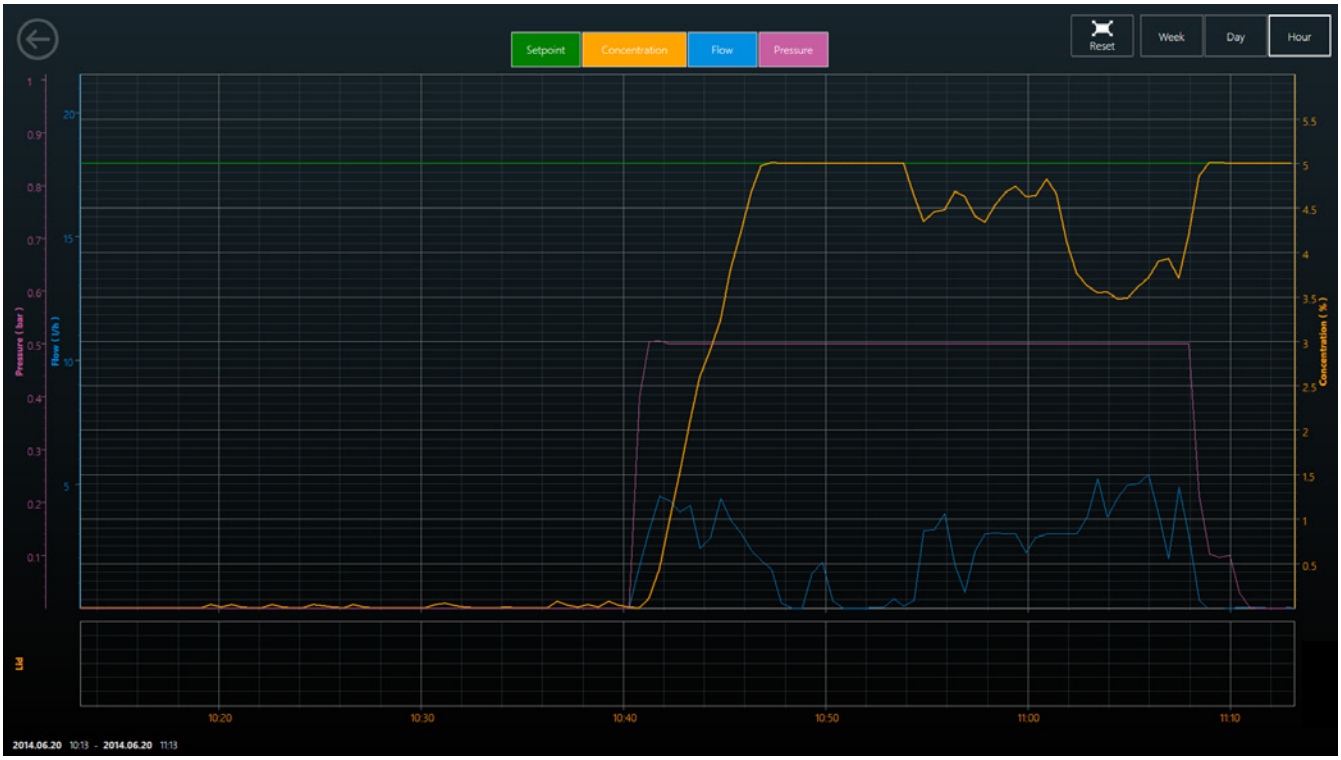


- Provides rapid temperature and gas recovery to ensure optimal environment stability.
- Premixed gas is no longer a requirement but an option and total gas consumption is very low.

Data And Alarms Logging

The MIRI® TL data logger continuously documents all incubation parameters such as flow, pressure, and concentration of CO_2, O_2 and temperature regulation data. Details of any alarm events such as out-of-range parameters are also stored for retrieval.

You can also view similar performance data right on your MIRI® TL Viewer Software on a daily or weekly basis for all chambers. Data can also be easily printed for record keeping/audits.



The data logger stores continuous performance data of your device throughout its use. These are viewed in graph form.

Conditions that put the MIRI® TL into alarm state are recorded. It is also possible to configure the software to send email alerts.

High Quality Environment for Optimum Embryo Growth

Advanced CO_2 + O_2 Regulation

Provides total control of the gas phase environment

The built-in gas mixer and the high-performance CO_2 and O_2 sensors allow accurate control of gas phase composition in the chambers.

Gas Recovery:
< 3 minutes

Gas Consumption:
CO_2: < 2 L/h
N_2: < 5 L/h

High Quality Recirculated Airstream

High Quality Airstream Via:

Volatile Organic Compounds or VOCs are toxic to an embryo. VOCs attach directly to DNA and this can be detrimental to embryo development. The MIRI® TL is specially equipped with HEPA/VOC filter to help eliminate harmful VOCs and particulates.

HEPA/VOC filter
254 nm UV-C with 185 nm filter

Easy Parameter Validation

Quality Checking an easy breeze!

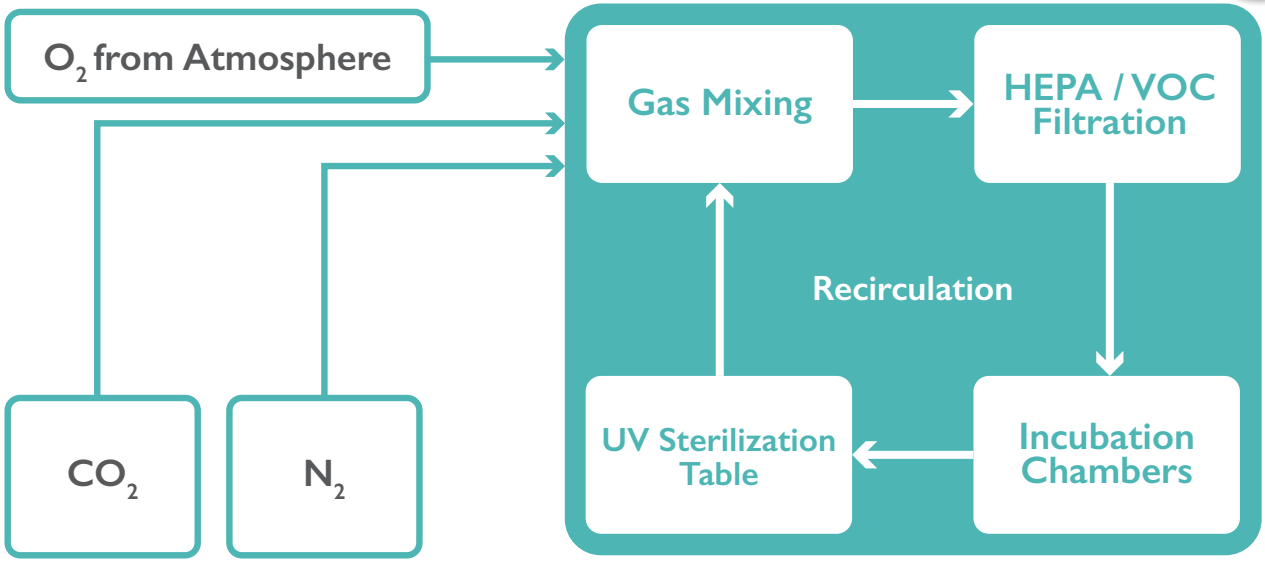
Each compartment has an individual PT1000 sensor and gas sample port specifically designed for independent and continuous validation of temperature and gas concentration. The TL range can be connected to a MIRI® GA, a Gas and Temperature Validation unit, for continuous external validation of both gas and temperature.

It also has a pH measuring system and a small validation well on the CultureCoin® for easy checking of the pH in each compartment.

MIRI-GA

The HEPA/VOC Filter can be easily removed for replacement. No hassle. No downtime.

Airflow Diagram



Input Gases and Mixing

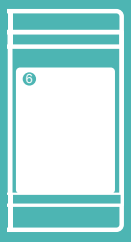
The MIRI® TL is a tri-gas system, which requires 100% CO_2, 100% N_2 and atmospheric Oxygen. The gases go through the built-in gas mixer, which regulates the concentration of CO_2 and O_2 in the culture chambers to the desired level. The gas levels are regulated according to the feedback loop from a NDIR CO_2 sensor and a medical grade chemical O_2 sensor. Nitrogen is infused to suppress the ambient O_2 level.

HEPA/VOC Filtration

The gases then go through the HEPA/VOC filter, which effectively removes Volatile Organic Compounds (VOCs) and particulates larger than 0.3 µm.

Incubation Chambers

The MIRI® TL features a recirculated gas system, whereby each of its chambers is constantly monitored for gas concentration and adjusted to the correct level. Gas is drawn from all the compartments and routed through a gas mixing chamber where the gas concentrations are adjusted to set point levels.



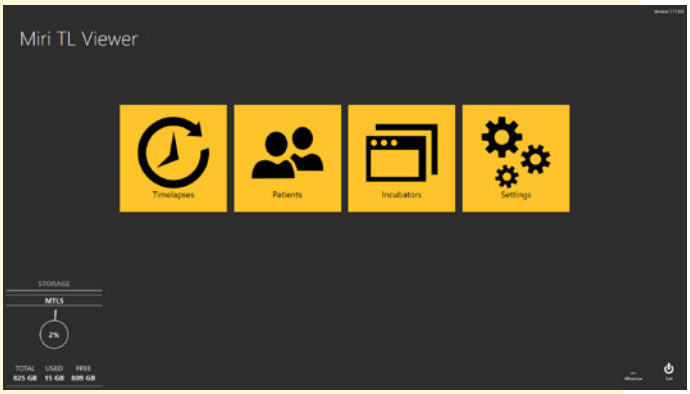
UV Sterilization

The circulated gas is subjected to a 254nm UV light exposure after passing through the mixing chamber and VOC/HEPA filtration. The UV-C light contains light filters that inhibit the production of dangerous ozone using 185nm radiation. UV-C light may be toggled ON or OFF as required by the user.

Embryo Analysis and Evaluation System

Simple and Intuitive

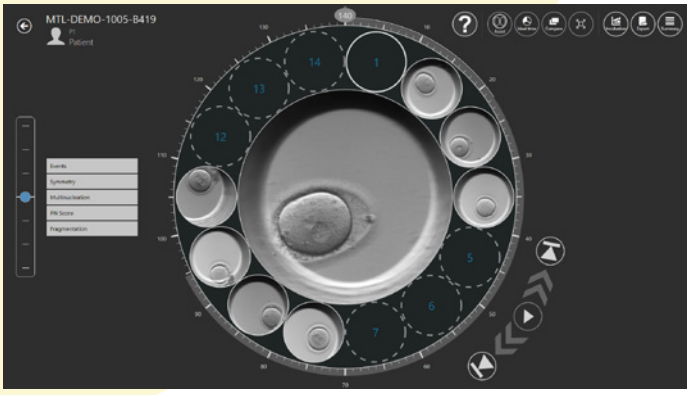
The MIRI® TL Viewer Software is a simple yet sophisticated and highly informative tool that can help embryologists process the data generated. You can review, annotate and compare the morphokinetic parameters of each embryo to select or deselect embryos for transfer while also allowing data export for retrospective analysis.



Complete Data Logging System

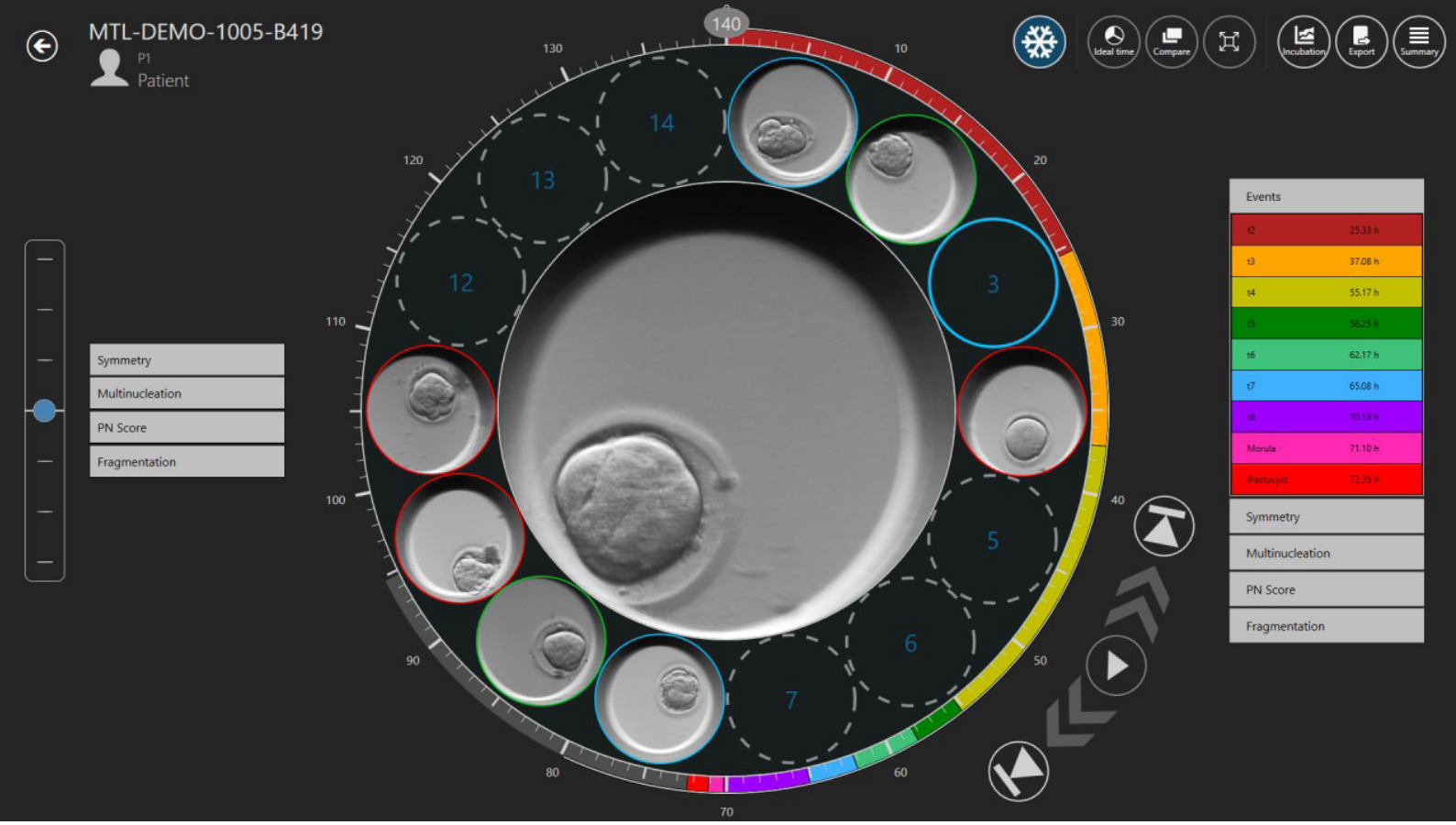
The main view shows four buttons:

- Timelapses (a list of pending, ongoing and past time-lapse sessions)
- Patients (Patient database)
- Incubators (view connected MIRI® Time-Lapse incubator)
- Settings (customize/s any annotation and ideal timing parameters)



Embryo Development Overview

Viewing embryo development has never been better. The *Revolver View* shows all embryos incubated within a CultureCoin®. This view is your starting point for annotation and selection. From here, you can choose an embryo to annotate and compare its development with other embryos in order to determine the most viable one.



Sophisticated Tools for Annotation

Embryo annotation made easy! The annotation system is structured around the "events" that are located to the left of the wheel. Annotation is the process of time-marking a specific event/ parameter e.g. if you've observed t2 happening at 27 hpi, you can click "t2" on the list of events from the left column and the annotated parameter of t2 at 27 hpi will be displayed in the right column. By default, the pre-programmed events list includes t2, t3, t4, t5, t6, t7, t8, morula, blastocyst and early blastocyst.

The sophisticated software gives the user the ability to customize each event completely. The events listed in the left column can be customized to include other parameters not programmed in the default settings. You can go to Settings where you can find more advanced parameters that can be included in your time-lapse grading system. To complement these features, we have added the Ideal Time function, in the form of a circular coloured band on the edge of the annotated events. This indicates their ideal timings, making it easier to compare the actual timing of the embryo development with the ideal.

Side-by-Side Comparison

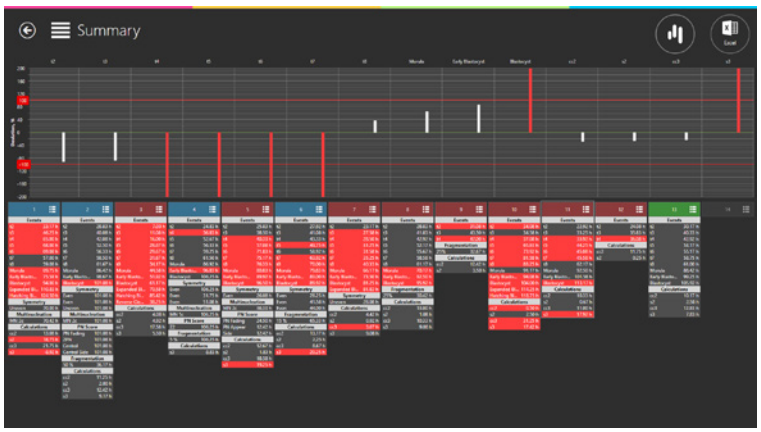
Choosing the most viable embryo for transfer is made easier with the **Compare Tool.** It allows you to make a side-by-side comparison of the embryo development and offers you the flexibility to choose the specific time point you would like to compare.

Easy to Understand Summary View

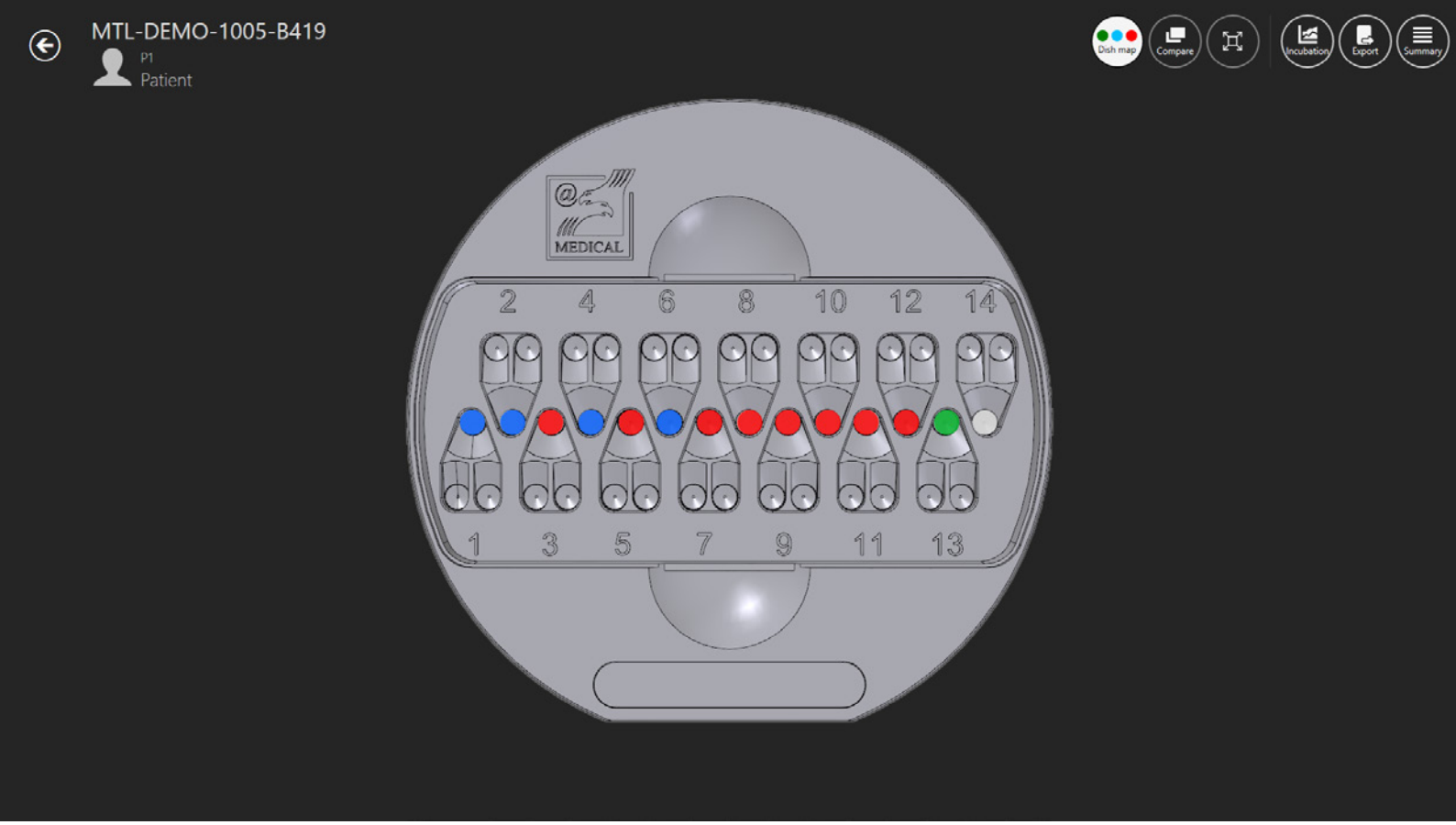
The **Summary View** is a helpful tool in comparing and selecting the most viable embryo based on the annotations made. The Horizontal View allows you to compare the actual cleavage timings of all embryos against the ideal timing.

Horizontal View

The Vertical View is an efficient way of identifying cleavage timings that are within or out of predetermined criteria (range). The white bar indicates timings within acceptable parameters while the red bar indicates those outside acceptable criteria.



Vertical View



Once the evaluation and comparison are complete, the embryos can be assigned colours that indicate their outcome:

A coloured ring will appear around the embryo well and the colour on the dish map will change accordingly.

White - No Decision

Blue - Freeze

Green - Transfer

Red - Discard

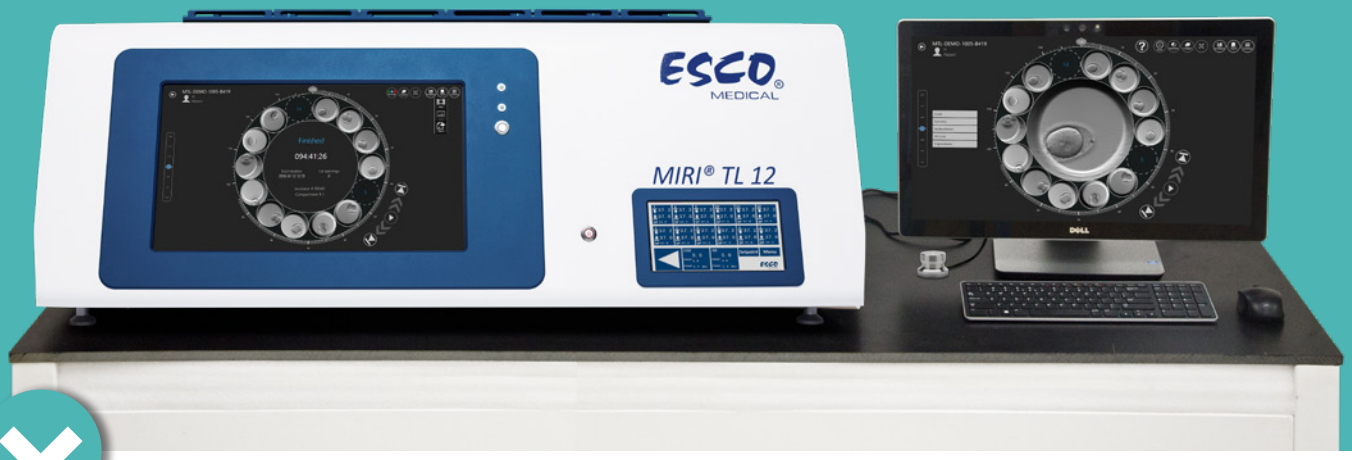
Freedom to Personalize

Our belief is that as the customer, the device belongs to you. Therefore, it should offer you the freedom to customize and adjust the instrument and parameter settings completely. The "Ideal Time" function and Events for the annotation can be optimized based on the requirements of your clinic.

The Time-Lapse incubator stays true to Esco's world class expertise and quality in IVF technology.

Make MIRI® TL a part of your IVF lab.

Monitor the MIRI® TL Incubator



MIRI® TL Viewer

The MIRI® TL Viewer is a specialized software platform that gives you the capability to visualize, compare (side-by-side), annotate and store the embryo development images coming from the MIRI® TL incubator. The logging software shows incubator status and provides you with the option to send e-mail alarms. At the same time, the MIRI® TL Viewer also serves as a video player for the time-lapse videos generated by the MIRI® TL incubator.

MIRI® TL Server

The MIRI® TL Server provides you with secure and high capacity storage of your TL data.

MIRI® TL Viewer Specifications

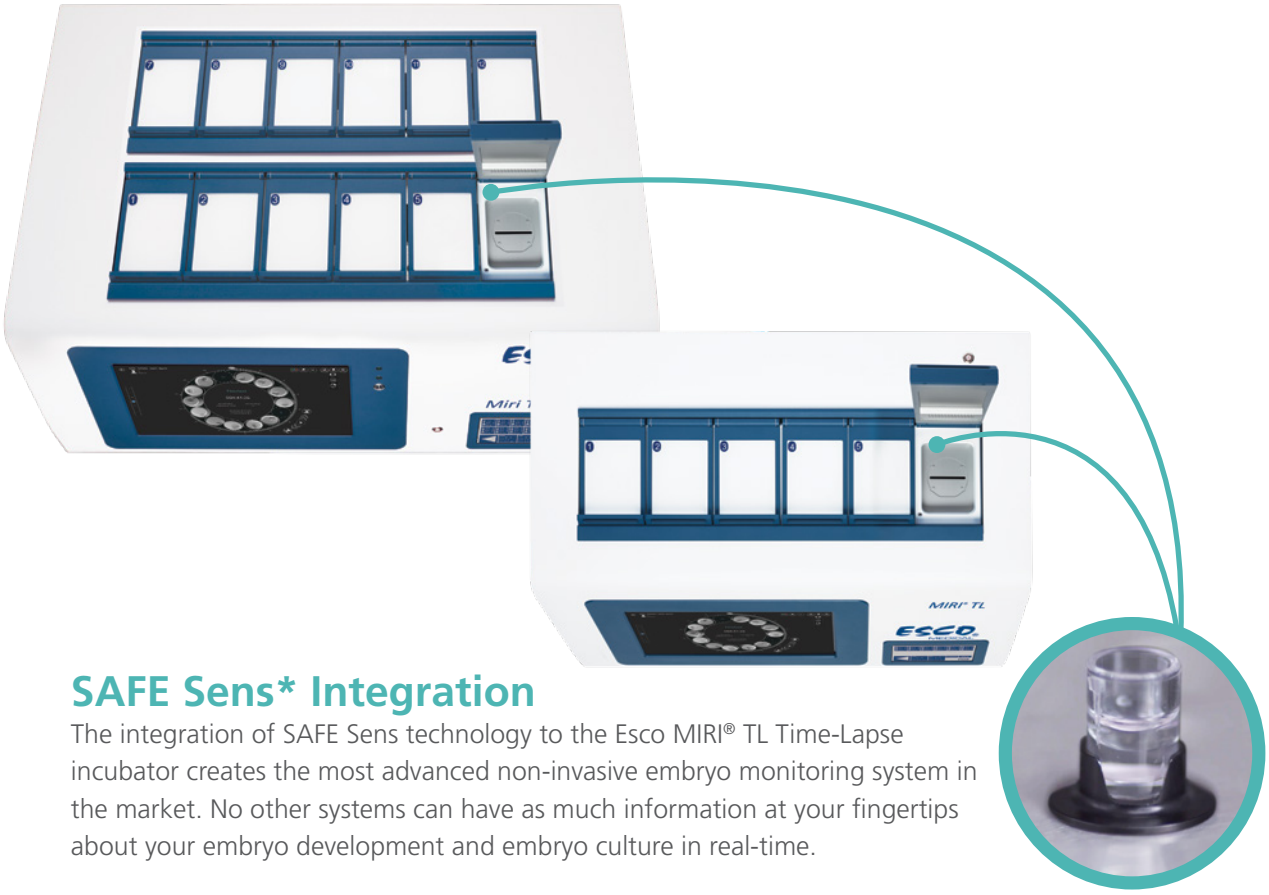
CPU	
CPU Model	Intel® Core™ i7-8700
CPU Architecture	64-bit
CPU Frequency	6-core, up to 4.6 GHz
Memory	
Installed Memory	1 x 8 GB
Memory Type	DDR4-2666 MHz non-ECC
Storage	
Installed	1000 GB
Storage Type	HDD

Operating System	
Manufacturer	Microsoft
Name	Windows 10 Pro x64
External Ports	
RJ-45 LAN Port	1 rear
USB 3.1 Type A Gen 1	4rear, 1 side (with PowerShare)
USB 3.1 Type C Gen 2	1 side
Audio	1 Line-Out (rear), 1 Universal Audio Jack (side)
Video	1 HDMI In, 1 HDMI Out, 1 DisplayPort Out, 1 USB-C (DP1.2)
Card Reader	microSDXC card slot

MIRI® TL Server Specifications

Database Storage	Intel® Core™ i5; 8 GB DDR4; 500GB SSD; Windows 10 PRO
Network Attached Storage	2 x 10 TB HDD - RAID 1; 500 GB SSD
Network Switch	16 port, Gigabit Ethernet

Never measure pH manually again. Monitor it with SAFE Sens.



SAFE Sens* Integration

The integration of SAFE Sens technology to the Esco MIRI® TL Time-Lapse incubator creates the most advanced non-invasive embryo monitoring system in the market. No other systems can have as much information at your fingertips about your embryo development and embryo culture in real-time.

Continuous pH measurement

- Reading and recording every 30 minutes (default setting - adjustable).
- Single use sensor probe for up to seven (7) days of pH readings.

Easy to implement

- Easy to align (no buffers, no hassles).
- Easy to use and maintain.

Data Logging System

- Data Logging and user alarms.
- Each TrakStation® can be connected to multiple incubators.

Compact and Efficient

- No more unnecessary openings of your incubator chamber for spot pH measurement.
- Only requires 100 µL of media + 150 µL of oil.

** SAFE Sens is a trademark brand of Blood Cell Storage, Inc. (BCSI). SAFE Sens integration is currently offered as a factory-installed option.*

Accessories

MIRI® TL | SV2 Sensor | QC2 Alignment Tool | SAFE Sens TrakStation

Notes:

(1) One QC2 alignment tool can be used on all incubators. If incubators are located in separate rooms, you may have to order more than one QC2 tool.

(2) QC2 Alignment tool and SV2 sensors have an expiration date of one (1) year.

(3) The MIRI® TL with SAFE Sens automatically comes with free one (1) pack of SV2 sensors, which is to be used for Site Standardization. Please determine how many additional packs you need for routine pH testing .

(4) One TrakStation can connect up to eight (8) incubators by using a USB 3.0 Hub.

General Specifications

MIRI® Time-Lapse Incubator

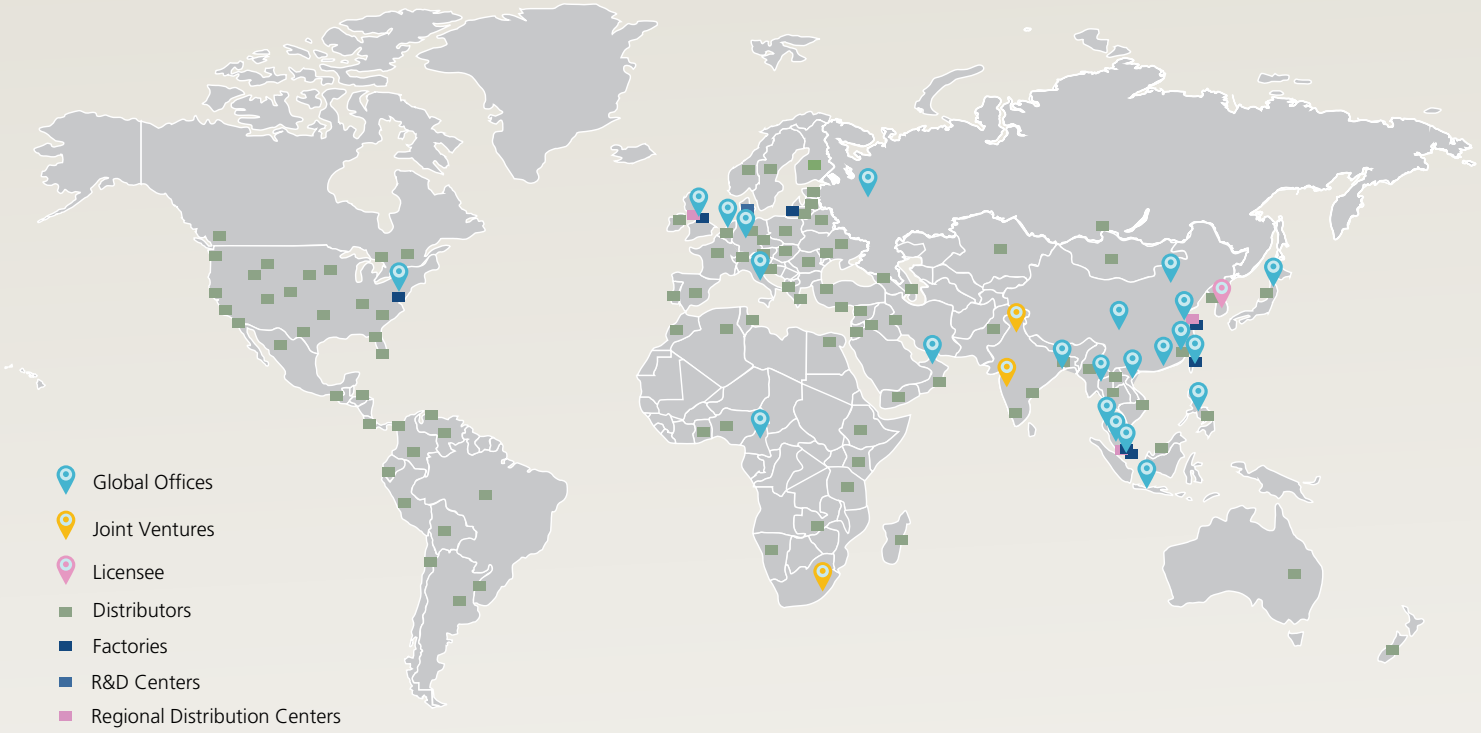
Specifications	TL6	TL12
Overall Dimensions	805 x 585 x 375 mm (31.7 x 23.0 x 14.8”)	950 x 685 x 375 mm (37.4 x 27.0 x 14.8”)
Weight	70 kg	100 kg
Temperature Control Range	25 - 40 °C	
Gas Consumption (CO_2) *	< 2 L/h	
Gas Consumption (N_2) **	< 5 L/h	
CO_2 Control Range	1.9 - 10%	
O_2 Control Range	5 - 20%	
Input Gas Pressure	0.6 bar (8.7 psi)	
Built-in Microscope	Zeiss 20x, objective has numerical aperture of 0.35, specialized for 635 nm illumination	
Embryo Illumination	0.064s per image, using 1W single red LED (635nm)	
Camera Resolution	1280 x 1024. Monochrome, 8-bit, IDS system	
Optics Tube Ratio	2.22 px/µm	
Imaging Focal Planes	5 min. image interval in 3 to 7 focal planes	

* Under normal condition (CO_2 set point reached at 5.0%, all lids closed).
** Under normal condition (O_2 set point reached at 5.0%, all lids closed).

Ordering Information

ITEM CODE	MODEL CODE	DESCRIPTION
Unit		
2070091	MRI-TL-MN-6C-8	MIRI® Time-Lapse Incubator, Mini, 6 Chambers, 230 V, 50/60 Hz
2070092	MRI-TL-MN-6C-9	MIRI® Time-Lapse Incubator, Mini, 6 Chambers, 115 V, 50/60 Hz
2070098	MRI-TL-MN-6C-SS-8	MIRI® Time-Lapse Incubator, Mini, 6 chambers with SAFE Sens, 230 V, 50/60 Hz
2070099	MRI-TL-MN-6C-SS-9	MIRI® Time-Lapse Incubator, Mini, 6 chambers with SAFE Sens, 115 V, 50/60 Hz
2070100	MRI-TL12C-8	MIRI® Time-Lapse Incubator, 12 Chambers, 230 V, 50/60 Hz
2070101	MRI-TL12C-9	MIRI® Time-Lapse Incubator, 12 Chambers, 115 V, 50/60 Hz
2070114	MRI-TL-SS-12C8	MIRI® Time-Lapse Incubator, 12 Chambers, 230V 50/60Hz, with SAFE Sens
2070115	MRI-TL-SS-12C9	MIRI® Time-Lapse Incubator, 12 Chambers, 110V 50/60Hz, with SAFE Sens
Accessories		
1320011	MRA-1007	HEPA + VOC filter (to be replaced every 3 months)
1320088	MRI-CC	CultureCoin® for Time-Lapse of 14 embryos (25 pcs. per pack)
1320045	MRI-GA	MIRI® GA CO_2/O_2 & Temperature Validation Unit, 115V/ 230V

ESCO GLOBAL NETWORK



Esco Medical Products:

MIRI® TL6 Time Lapse Incubator
MIRI® TL12 Time Lapse Incubator
MIRI® Multiroom Incubator
MIRI® II Multiroom Incubator
Mini MIRI® Incubator
Esco Multi-Zone ART Workstation
Esco Multi-Zone ART Workstation Class II
Semi-Closed Environment IVF
CelCulture® CO_2 Incubator
MIRI® GA (Gas and Temperature Validation Unit)
Anti-Vibration Table (AVT)

Infertility is a problem that has a significant social, psychological, and economic impact on afflicted individuals and couples. It is a global concern that knows no race or creed. It has been estimated that 1 in 6 couples struggle with infertility at least once in their lifetime.

Esco Medical is one of the divisions of the Esco Group of Companies. We provide innovative technological solutions for fertility clinics and laboratories. We aim to become the leading manufacturer of high-quality equipment such as long-term embryo incubators, ART workstations, anti-vibration tables, and time- lapse incubators.

Our products are designed with the Silent Embryo Hypothesis as a guiding principle. The Silent Embryo Hypothesis states that the less disturbed an embryo can remain, the better its developmental potential will be. Most of our products are designed in Denmark and made in the EU. Our primary focus is to increase pregnancy success rates and patient satisfaction.

ESCO MEDICAL Life has begun

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Esco Global Offices: Bangladesh | Cameroon | China | Denmark | Germany | Hong Kong | India | Indonesia | Italy | Japan | Lithuania | Malaysia | Myanmar | Philippines | Russia | Singapore | South Africa | South Korea | Taiwan | Thailand | UAE | UK | USA | Vietnam

Designed in Denmark Made in the E.U.

9010338_MIRI® TL_Combined_Catalogue_A4_vD_100319

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PT. Esco Bintan Indonesia Certificate No: 651333/E
PT Esco Bintan Indonesia Cert. No: QJN13038379/7001