

EMBRYOSCOPE™ TIME-LAPSE SYSTEM



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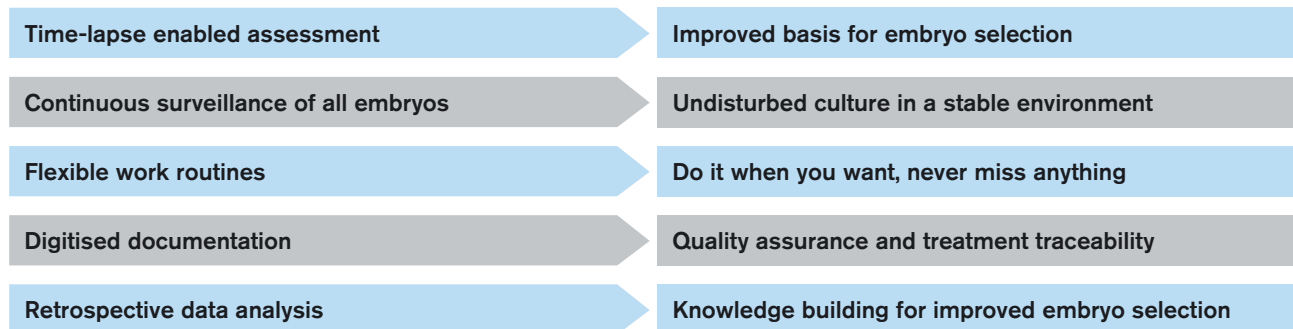
CE – Class IIa Medical Device
FDA 510(k) cleared for clinical use



EMBRYOSCOPE™ TIME-LAPSE SYSTEM

Traditionally, assessment of embryo selection in IVF is limited to brief “snap-shot” glimpses at defined time-points in order to minimise disturbances to culture conditions. However, embryo development is a dynamic process and a wealth of information about embryo development history remains untapped.

Improved IVF treatment through:



EMBRYOSCOPE™

TIME-LAPSE INCUBATOR

Undisturbed stable incubation

- Tri-gas incubator allows fast and accurate regulation of CO₂ and O₂ concentrations with minimal gas consumption
- Unique temperature control by direct heat transfer to individual media-filled wells. Temperature is virtually unchanged by opening chamber (<0.2° C) when adding or removing patient samples
- Recovery of CO₂ concentration in less than 5 minutes and O₂ in less than 15 minutes after closing chamber
- Continuous circulation and purification of air supply with residence time of less than 20 minutes
- Air purified by active carbon and HEPA filter. Removes VOCs and retains 99.97 % of particles larger than 0.3 µm
- Simplifies compliance with EU Directive 2004/23/EC by automatic logging of running conditions such as temperature, CO₂ and O₂ concentration to patient data files
- Dry incubation without water pans eliminates problems with water condensation and fungal growth on surfaces in high humidity

Time-lapse monitoring

- Fully automated detection and focusing of up to 72 embryos (6 patient culture dishes with 12 embryos in each dish)
- Image acquisition in multiple focal planes of all embryos
- High-quality Hoffman modulation contrast optics allows observation of key morphological features
- Special Leica optics designed for red light at 635 nm to eliminate high energy light exposure

Embryo selection

Use both morphological and morphokinetic observations to select the best embryo:

- Fertilisation events
- Exact timings of cleavages
- Exact timing of morula and blastocyst stages
- Synchrony of divisions
- Occurrence and type of multinucleation
- Fragmentation history



EMBRYOVIEWER® SOFTWARE

With the EmbryoViewer software, you can review, annotate and compare development of selected embryos from data acquired by the EmbryoScope time-lapse incubator. Instrument running conditions are automatically stored with the patient data and can be observed on the EmbryoViewer software for quality assurance.

Flexible work routines

- Observe and assess patient embryos from your office via the ES server
- Instantly access current patient data for assessment

- Facilitates consultation with patients and colleagues
- Technical, laboratory and patient reports are easily generated by the EmbryoViewer software

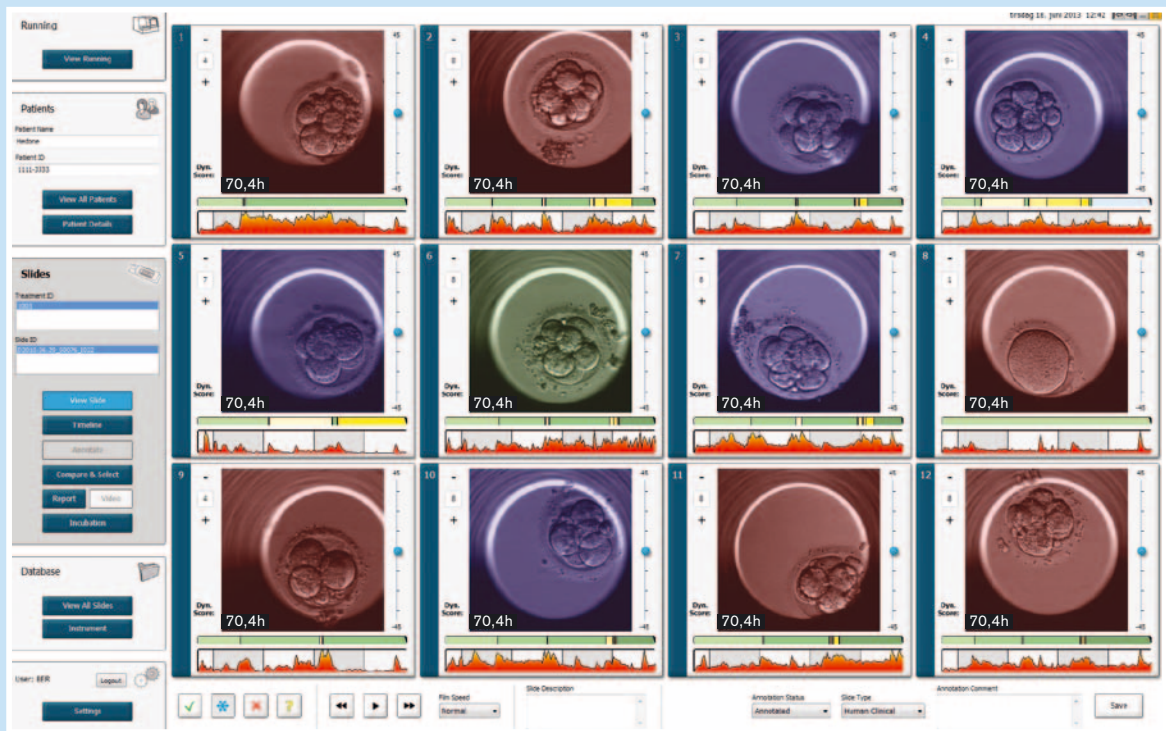
Quality assurance

View data from ongoing or finished treatments to access embryo development videos, patient data and instrument performance.



Improved basis for embryo selection

View and compare all patient embryos from an EmbryoSlide culture dish at the same time. Select a single embryo for annotation or use [View slide](#) to perform a side-by-side comparison of all embryos in a culture dish. Export video and images of interest for presentations and discussions.






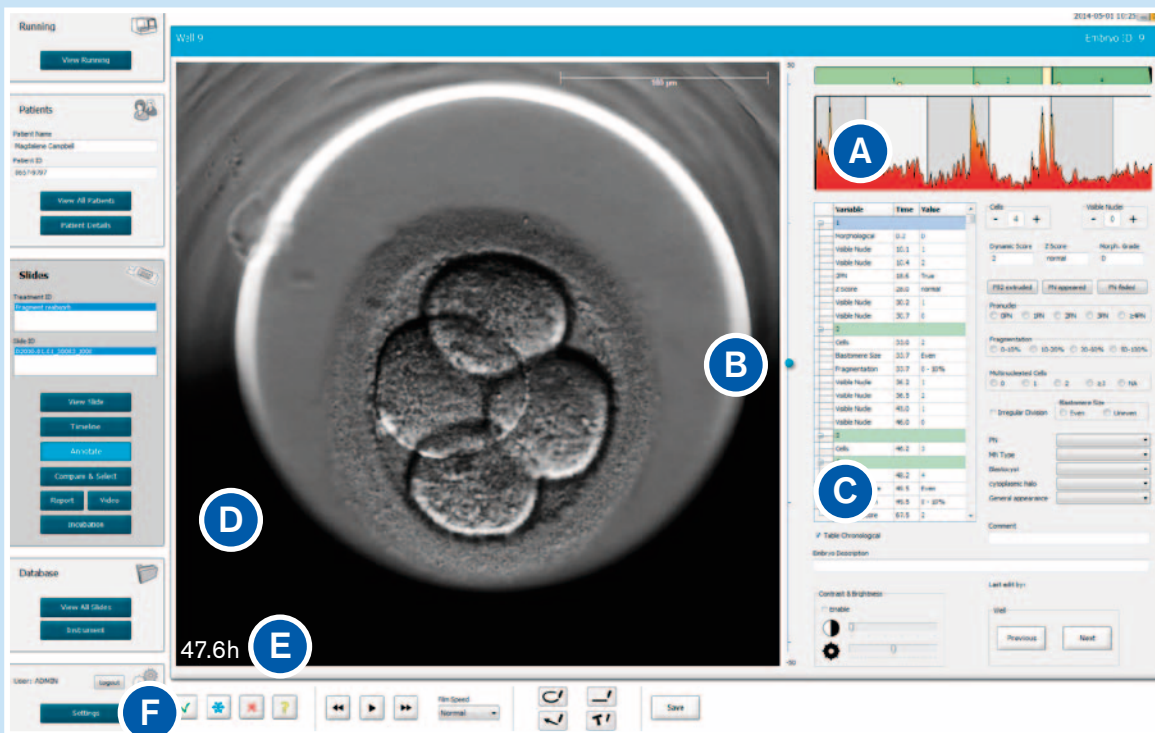
Delivered with a jog wheel for ease of video replay



Intuitive annotation tools

Manual annotation of cell division events is displayed in the table providing an easy overview of observations in developmental stages

- A** Automatically calculated cellular activity indicating cell division events (patented)
- B** Select different focal planes to refocus and to observe details of interest
- C** All annotations and notes are saved for future reference
- D** High quality Hoffmann modulation contrast images allows observation of key morphological events
- E** Elapsed time from insemination
- F** Select a button to indicate which embryo to  transfer,  freeze or  discard.



ANNOTATE view allows detailed synchronised time-lapse comparison of up to three embryos

Assisted embryo selection

Set up one or more models according to clinic specific criteria and rank embryos accordingly using the **Compare & Select** view.

Designing a model

A Create customised models to reflect difference between clinics (conditions, day of transfer etc.)

Set up selection, deselection or information criteria to define a model

B Set up custom expressions to define model variables

A Definition

Variable	Weight	Min	Max	Description	P(Variable)
NOT2PN	-100			Avoid	-100, 0, if NOT2PN is TRUE if NOT2PN is FALSE
Cells28h	1	2.0	2.0	Prefer	1, 0, if 2.0 ≤ Cells28h ≤ 2.0 if 2.0 > Cells28h or Cells28h > 2.0
Cells44h	1	4.0	4.0	Prefer	1, 0, if 4.0 ≤ Cells44h ≤ 4.0 if 4.0 > Cells44h or Cells44h > 4.0
Cells68h	1	8.0	8.0	Prefer	1, 0, if 8.0 ≤ Cells68h ≤ 8.0 if 8.0 > Cells68h or Cells68h > 8.0
Direct	-10	0.0	8.0	Avoid	-10, 0, if 0.0 ≤ Deselect ≤ 8.0 if 0.0 > Deselect or Deselect > 0.0
MV2	0			Information	
MV4	0			Information	

B Custom Expression

Name: Custom Expression

Direct:

Help:

Variable:

Function:

Name: = Expression:

Help: Variables: tPB2, tPNa, tPNf, t2, t3, t4, t5, t6, t7, t8, t9, tM, tSB, tEB, tHB
Functions: cells(t) E.g. number of cells at 48 hours: cells(48)

Applying a model

Using **Compare & Select** embryos are easily ranked according to a specific model.

C Choose model from drop-down list

D Calculated model score

E View the embryo ranking

C

D

Embryo	Current	NOT2PN	Cells28h	Cells44h	Cells68h	Direct	MV2	MV4	Embryo	Embryo	Embryo	Embryo
1	47.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	1	2	3	4
2	14.3	0.0	2.0	4.0	8.0	0.0	0.0	0.0	5	6	7	8
3	18.5	0.0	2.0	4.0	8.0	0.0	0.0	0.0	9	10	11	12
4	15.3	0.0	2.0	4.0	8.0	0.0	0.0	0.0	13	14	15	16
5	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	17	18	19	20
6	13.7	0.0	2.0	4.0	8.0	0.0	0.0	0.0	21	22	23	24
7	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	25	26	27	28
8	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	29	30	31	32
9	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	33	34	35	36
10	14.3	0.0	2.0	4.0	8.0	0.0	0.0	0.0	37	38	39	40
11	13.7	0.0	2.0	4.0	8.0	0.0	0.0	0.0	41	42	43	44
12	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	45	46	47	48
13	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	49	50	51	52
14	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	53	54	55	56
15	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	57	58	59	60
16	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	61	62	63	64
17	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	65	66	67	68
18	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	69	70	71	72
19	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	73	74	75	76
20	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	77	78	79	80
21	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	81	82	83	84
22	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	85	86	87	88
23	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	89	90	91	92
24	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	93	94	95	96
25	7.0	0.0	2.0	4.0	8.0	0.0	0.0	0.0	97	98	99	100

E

KIDScore™ D3 Basic decision support tool

KIDScore D3 Basic is a model based on the morphokinetic traits associated with the implantation potential of embryos transferred on day 3. The model is designed to help clinics avoid transferring embryos with low implantation potential.

KIDScore D3 Basic is robust, safe and easy to use and will provide the immediate benefit of using time-lapse for embryo evaluation. The model has been validated for day 3 transfers in a wide range of clinics.

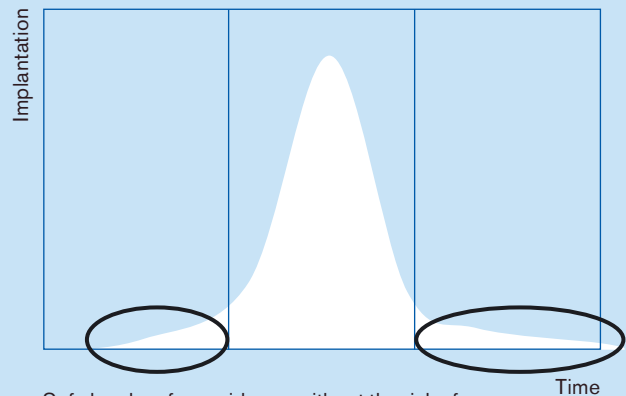
Key benefits

- Does not require Known Implantation Data (KID) to start enjoying benefits of time-lapse for embryo evaluation
- Robust model, which can be safely used by a wide range of clinics
- Easy to use model with only a few variables to annotate

Principles of KIDScore D3 Basic

KIDScore D3 Basic is based on morphokinetic information from more than 3300 embryos with known implantation status after a day 3 transfer.

KIDScore D3 Basic : a safe first model using avoidance criteria rather than selection criteria



Safe borders for avoidance without the risk of excluding embryos with good potential

This large dataset makes it possible to distinguish broad statistical patterns that are generally applicable. KIDScore D3 Basic is designed as an Avoidance model. This means that embryos ranked low by the model have a statistically low chance of implanting. In comparison, embryos ranked high by the model have a statistically higher chance of implanting. As KIDScore D3 Basic is based solely on morphokinetic information, morphology should always be taken into consideration.

Practical usage

The use of KIDScore D3 Basic is based on a few simple annotations performed on the EmbryoViewer software.

Applying KIDScore D3 Basic

Select an active EmbryoSlide culture dish and go to the Compare & Select page of the EmbryoViewer software.

- A** From the Model drop-down menu at the top of the page, select "KIDScore D3 Basic".
- B** Each embryo will be assigned a score from 0 to 5 based on the annotations and the avoidance criteria of the model.

Embryo ID	Score	Avoidance
Embryo ID: 1	4	0
Embryo ID: 2	1	9+
Embryo ID: 3	4	0
Embryo ID: 4	3	9+
Embryo ID: 5	5	0
Embryo ID: 6	2	0
Embryo ID: 7	5	0
Embryo ID: 8	3	9+

EMBRYOSLIDE® CULTURE DISH

Unique identification of each embryo

Micro-numerals next to well bottom visible in dissection microscope during embryo handling (patent pending)

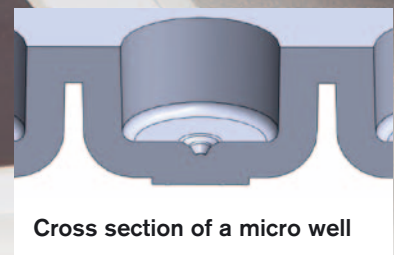
Safe and easy handling

- Embryo settles at the bottom of the well. Conical sides of the well automatically place the embryo in a central depression with a diameter of 0.2 mm for direct thermal contact with a heated tray holder
- Vertical “tail-fin” ensures a firm grip and safe handling
- Separate lid with small fins for easy detachment
- Facilitates sampling of spent media for subsequent analysis of proteome or secretome (patented)
- Compatible with standard microscopy

- Standard slide format (25 x 75 mm)
- Optical grade polymer optimised for microscopy
- 4 small wells designed for flushing of the embryos (this feature is currently not available in the US)

Safe, non-humidified environment

Water impermeable polymer slide and cover of immersion oil prevent dehydration during handling in low humidity laboratory air and in dry incubators



Cross section of a micro well

ES SERVER

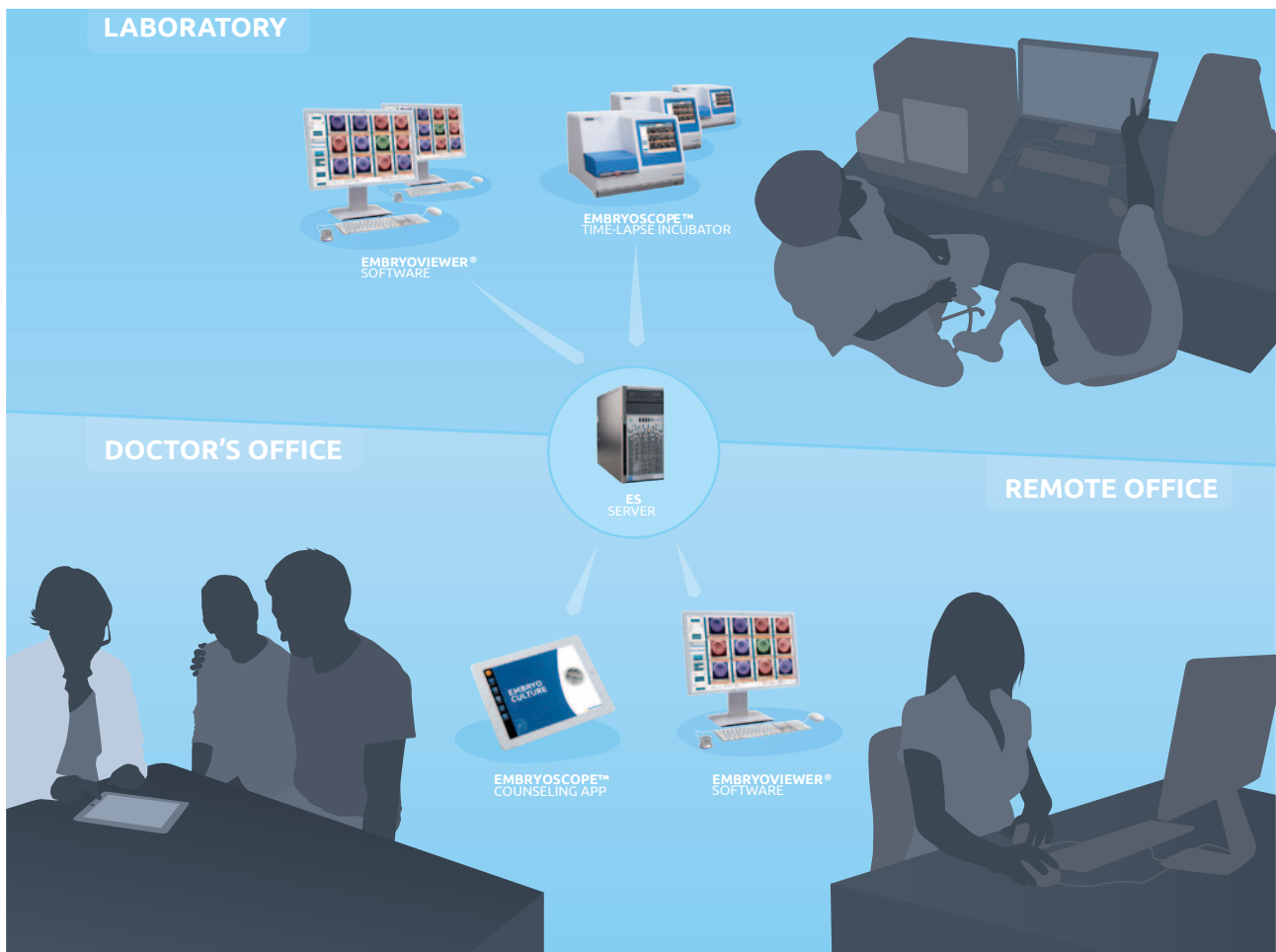
Expand your possibilities

ES server provides the storage and infrastructure hub to run various applications associated with the EmbryoScope time-lapse system.

The server is designed to support a range of new applications including the EmbryoScope Counseling App and a patient barcode labeling system. New features and applications will use the capabilities provided by the ES server – the main building block of your network.

The ES server is a powerful platform which enables access to your data. Time-lapse data is stored on the ES server from all connected EmbryoScope time-lapse incubators and accessed from multiple EmbryoViewer workstations. Authorised users can even access the data stored on the server from another clinic or another remote location using a secure connection. This enables users to view, annotate and select embryos with geographical flexibility, thereby enhancing productivity.

Europe: CE-marked class I medical device
Currently not available in the US



Main capabilities

Flexible workflow

- Single database for analysis
- Connect from two or more EmbryoViewer workstations
- Access from remote locations through a secure connection (min. 100mbit)

Multiple users can annotate simultaneously

Remote office features

- View and review embryo development
- Embryo annotation
- Embryo selection
- Data export
- Video export

Typical storage capacity: 2500 treatments (upgradable)

Add-on features

- Inform patients about their IVF treatment and development of their embryos with the EmbryoScope Counseling App
- Annotate embryos from multiple EmbryoViewer workstations



EMBRYOSCOPE™ COUNSELING APP

Improve your patient communication

The EmbryoScope Counseling App offers the capability of educating your patients about embryo development and the ability to show patients the videos of how their own embryos developed in the EmbryoScope time-lapse incubator.

- An ideal tool for patient consultation
- Guide patients through the EmbryoScope time-lapse system treatment benefits versus standard incubation
- Show examples of a patient's developing embryos
- Show examples of good and poor developing embryos
- Log in to show patients how their own embryos have developed

The capability of showing patients their own embryos requires an annual ES server connection license for each device used.

Find the “EmbryoScope Counseling App” on the App Store on your iPad and get free access to the app's main features.



TECHNICAL SPECIFICATIONS

EmbryoScope™ time-lapse incubator

Instrument

Capacity	Six disposable EmbryoSlide® culture dishes holding 12 embryos each
Operation	Individual culture dishes may be inserted and removed independently
Dimensions	W x D x H (60.3 x 56.0 x 43.5) cm / (23.7 x 22 x 17.2) in
Weight	60 kg / 121 lbs
Input voltage	110-240 V AC
Power consumption	120 W
Operating range	20 °C – 30 °C
Alarm system	Continuous internal system integrity check for separate subsystems of the instrument. Monitoring of incubation conditions and subsystem integrity; audible and visible alerts when incubation conditions out of range.

Image acquisition

Focal planes	Select up to 17 focal points at each time point in user defined vertical increments Allowed number of focal planes depend on selected cycle time
Built-in microscope	Leica 20x, 0.40 LWD Hoffman modulation contrast objective specialised for 635 nm illumination
Camera resolution	1280 × 1024 pixels, 3 pixels per µm, monochrome, 8-bit
Embryo illumination	≤ 0.032s per image using single red LED (635nm) gives 34µW cm ⁻² for image acquisition
Time between acquisitions	10 min. cycle time for 7 focal planes, 2 min cycle time with single focal plane

Tri-gas incubator

Integrated in instrument

Temperature	30 °C to 45 °C ± 0.2 °C* * Temperature range: Temperature set-point must be at least 7 °C above ambient temperature and ambient temperature must be less than 30 °C
Oxygen	5 % to 20 % ± 0.3 %
CO₂	2 % to 10 % ± 0.2 %
Active air circulation	Full purification of gas volume every 20 minutes
Volatile organic compounds	Removed by active carbon filter
Particles	Removed by HEPA filter which retains 99.97 % particles >0.3 µm

Data acquisition

Intel based fanless embedded PC

Network	100 Mb Ethernet
Operating system	Microsoft Windows®
Data exchange	Ethernet
Data format for images	JPEG
Monitor	12.1" embedded touch screen

Europe: CE-marked class IIa medical device USA: FDA 510(k) clearance

EmbryoViewer® software

PC	Powerful small form factor PC
PC dimensions	W x D x H (3.5 x 18.0 x 18.0) cm / (1.4 x 7.1 x 7.1) in
Display dimensions	W x D x H (58.0 x 21.0 x 42.0) cm / (22.8 x 8.3 x 16.5) in
Weight	1.3 kg / 2.8 lbs
Input voltage	110-240 V AC
Jog wheel	Delivered with for ease of video replay
Data export	Patient and annotation data can be exported to Excel format for further data processing
Image export format	JPEG
Video export format	AVI

Europe: CE-marked class I medical device USA: FDA 510(k) clearance

ES server

Dimensions	W x D x H (17.5 x 47.52 x 36.82) cm / (6.9 x 18.7 x 14.5) in
Weight	18.96 kg / 41.79 lbs
Input voltage	AC 120/230 V (50/60 Hz)
Capacity	Typically 2500 treatments (upgradable). Depends on image acquisition settings.

Europe: CE-marked class I medical device

EmbryoSlide® culture dish (design protected)

Mirco well culture	12 numbered wells for incubation of individual embryos in droplets with 25 µl media 4 wells for flushing of embryos Separate compartments for embryo with media, under a common oil reservoir No need for humidified environment
Microscopy	Fully compatible with standard and inverted microscopes
Size	Standard slide format (25 × 75 mm)
Packaging	Dust free packing pouches 2D barcode for batch specification
Sterilisation method	E-beam sterilised according to ISO 11137 with SAL 10 ⁻⁶ Single use, sterile
Toxicity test	Embryotoxicity tested with 1-cell mouse embryos – minimum 80% expanded blastocysts after 96 hrs Cytotoxicity test according to ISO 10993-5 Non-pyrogenic
Labeling	Barcode labels for easy tracking (Optimal add-on, ES server required)

Europe: CE-marked class IIa medical device USA: FDA 510(k) clearance

TOGETHER. ALL THE WAY™

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