

EmbryoScope™
Time-lapse System

Continuous surveillance of all embryos

EmbryoViewer™
Workstation

Complete 4D documentation

EmbryoSlide®
Culture Dish

Safe and secure embryo handling

The Vision
to Conceive



Unisense Fertilitech A/S



Key Benefits

TIME-LAPSE ENABLED ASSESSMENT

– dynamic observation for better decisions

CONSTANT SURVEILLANCE OF ALL EMBRYOS

– undisturbed culture in a stable environment

FLEXIBLE EVALUATION

– do it when you want, never miss anything

COMPLETE 4D DOCUMENTATION

– knowledge building through retrospective analysis



About us

Unisense FertiliTech A/S was founded in 2003 as a subsidiary of Unisense A/S, to develop technology to improve human embryo assessment in assisted reproduction. Initial research using bovine models led the way to collaborations with embryologists in Europe and North America to evaluate our technology for use with human embryos. Towards this end, an instrument incorporating a fully stable incubation environment with integrated time-lapse image acquisition and respiration was developed.

Unisense FertiliTech is currently focusing on the very promising area of morphokinetic embryo assessment, and has developed, and manufactures the EmbryoScope™ Time-lapse system. The company is involved in numerous international collaborations, and strives to develop embryo assessment algorithms to improve embryo selection and workflow in the assisted reproduction laboratory.

The quality system at Unisense FertiliTech A/S conforms to the requirements in DS/EN ISO 13485:2003 + AC:2009 for production, installation and servicing of IVF incubators and related accessories.

“The Vision to Conceive”. Our goal is to promote knowledge building through extensive documentation and retrospective analysis. We are dedicated to providing technology to improve IVF treatment through quantification of embryo development patterns.

What do your embryos
do when you are sleeping?



EmbryoScope™ Time-lapse System

The Vision to Conceive

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

The EmbryoScope™ Time-lapse System provides a safe, controlled culture environment, while allowing continuous monitoring and observation of up to 72 embryos at a time. The instrument provides a unique opportunity to develop new parameters for future embryo scoring.

TIME-LAPSE ENABLED ASSESSMENT

– dynamic observation for better decisions

- Fully automated detection and focussing of up to 72 embryos (6 patient slides with 12 embryos in each slide)
- Image acquisition in multiple focal planes of all embryos every 20 min *
- 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
- Automatically calculated blastomere activity show movement between frames (patent pending).

* faster if fewer slides or focal planes are used

EMBRYO SELECTION

Use all conventional assessment parameters with the addition of novel time-lapse enabled parameters including:

- Exact timing of first and subsequent cleavages
- Synchrony of divisions
- Fragmentation history
- Appearance of nuclei after division
- Detection of multinucleation throughout development from one to multiple cells

CONSTANT SURVEILLANCE OF ALL EMBRYOS

- undisturbed culture in a stable environment

- Less manipulation of embryos reduces risk of accidents and contamination
- Built-in tri-gas incubator allows fast and accurate regulation of CO₂ and O₂ concentrations, with minimal gas consumption <1.0 L CO₂/hr)
- Unique temperature control by direct heat transfer to individual media-filled wells. Temperature is virtually unchanged by opening chamber (<0.2 °C)
- Recovery of CO₂ concentration in less than 5 minutes and O₂ in 15 minutes after closing chamber
- Continuous circulation and purification of air supply with residence time of less than 20 minutes.
- Air purified by Whatman® Carbon Cap™ active carbon and HEPA filter. Removes VOCs and retains 99.97% of particles greater 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



FLEXIBLE EVALUATION

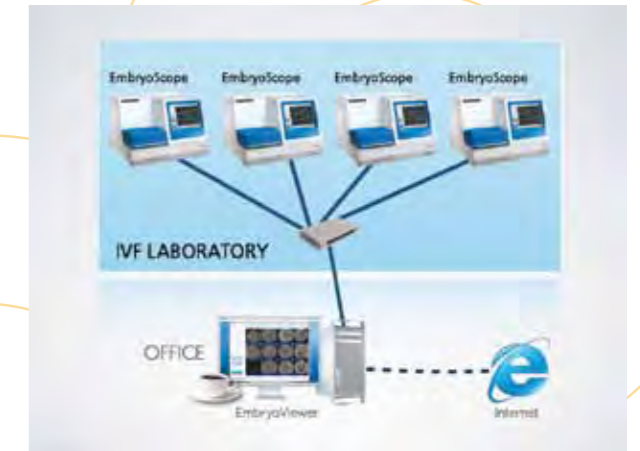
– do it when you want, never miss anything

- Instant and continuous updated overview of all patient embryos
- Intuitive touch screen interface allows selection of individual embryos for observation of development history
- Refocus in multiple planes, replay time-lapse, or use “Live view” to assess embryo quality directly
- Flexible timing for embryo scoring means improved time and resource management

COMPLETE 4D DOCUMENTATION

– knowledge building through retrospective analysis

- Time-lapse images and all incubation parameters are automatically stored in a patient file for review at any time
- Use the EmbryoViewer™ software to review, annotate, and compare synchronized time-lapse movies from current and previous patient embryos
- Opportunity to optimize and develop new assessment parameters



What do your embryos do when you are sleeping?

EmbryoViewer™ Workstation

The EmbryoViewer™ workstation is pre-installed with our exclusive software which allows observation and assessment of embryo development in real time. It also includes the advanced analysis tools for knowledge building through retrospective analysis of previous patient files.

With the EmbryoViewer™ software, you can review, annotate and compare development of selected embryos using data files acquired by the EmbryoScope™ Time-lapse System.

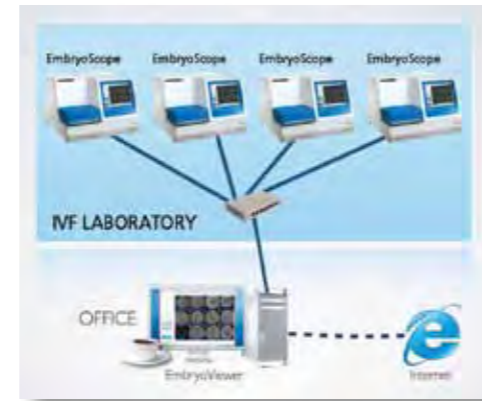
Benefits

- Flexible and convenient embryo assessment
- Easy navigation of patient files, time-lapse embryo development and instrument running conditions directly from your office.

Flexible Evaluation

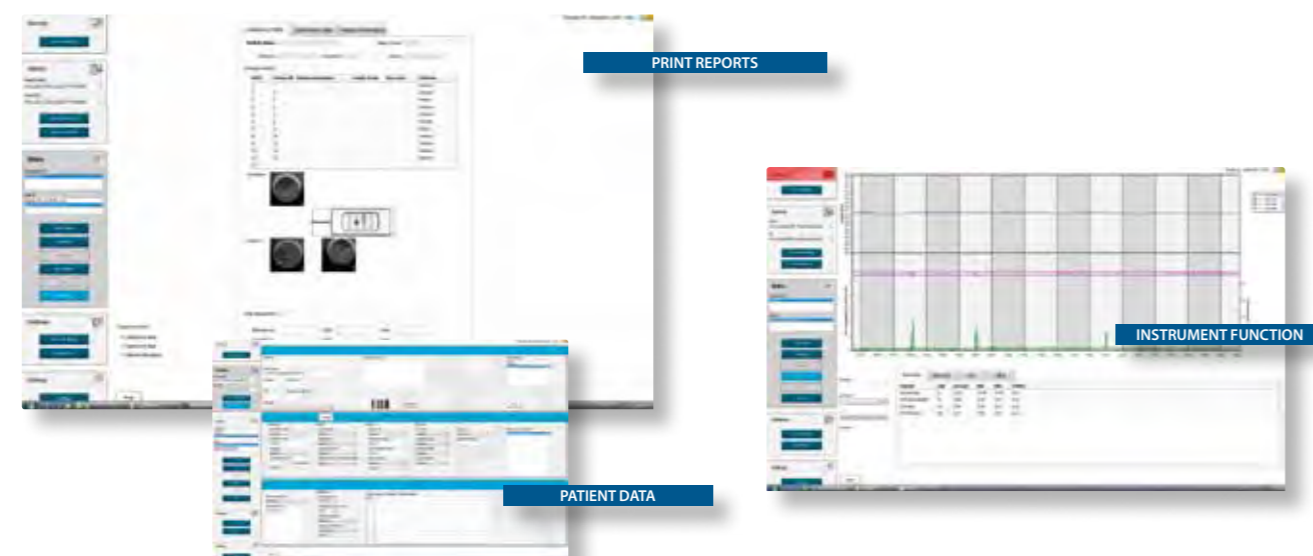
– do it when you want, where you want and never miss anything.

- Observe and assess patient embryos from your office via a dedicated Ethernet connection between the EmbryoScope™ Time-lapse System and EmbryoViewer™ Workstation
- Instantly access current patient data for assessment
- Facilitates consultation with patients and colleagues
- Reports generated by the EmbryoViewer™ software can be used in the laboratory to ensure the selected embryo is transferred
- Store and distribute images and time-lapse movies of embryo development may be used in communication with patients



Easy navigation to access all information

Select embryo development files from live experiments or finished saved data files to access embryo development videos, patient data and instrument function.

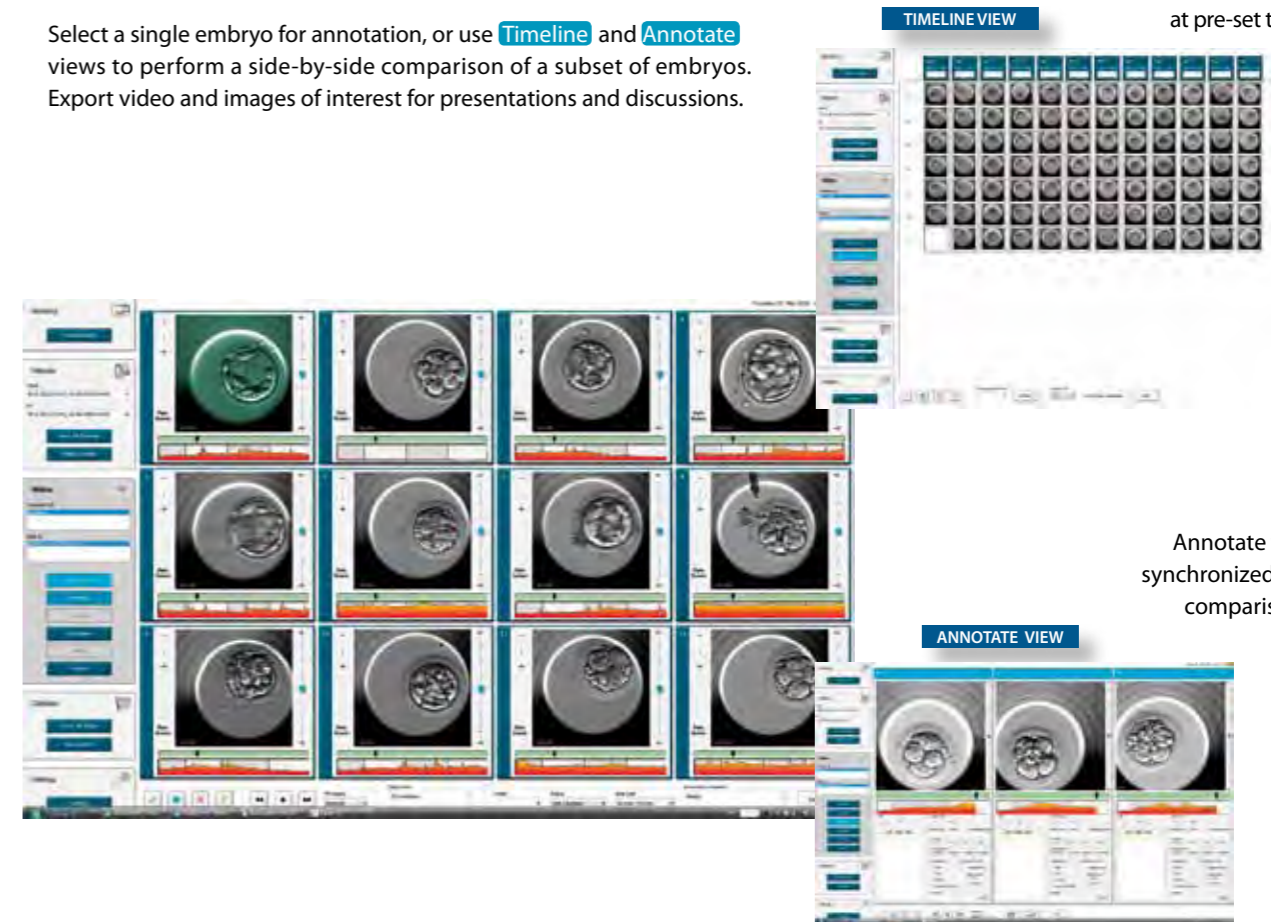


Advanced embryo analysis

– knowledge building through retrospective analysis

Select a single embryo for annotation, or use **Timeline** and **Annotate** views to perform a side-by-side comparison of a subset of embryos. Export video and images of interest for presentations and discussions.

Timeline allows selection of multiple embryos fast comparison at pre-set timepoints.

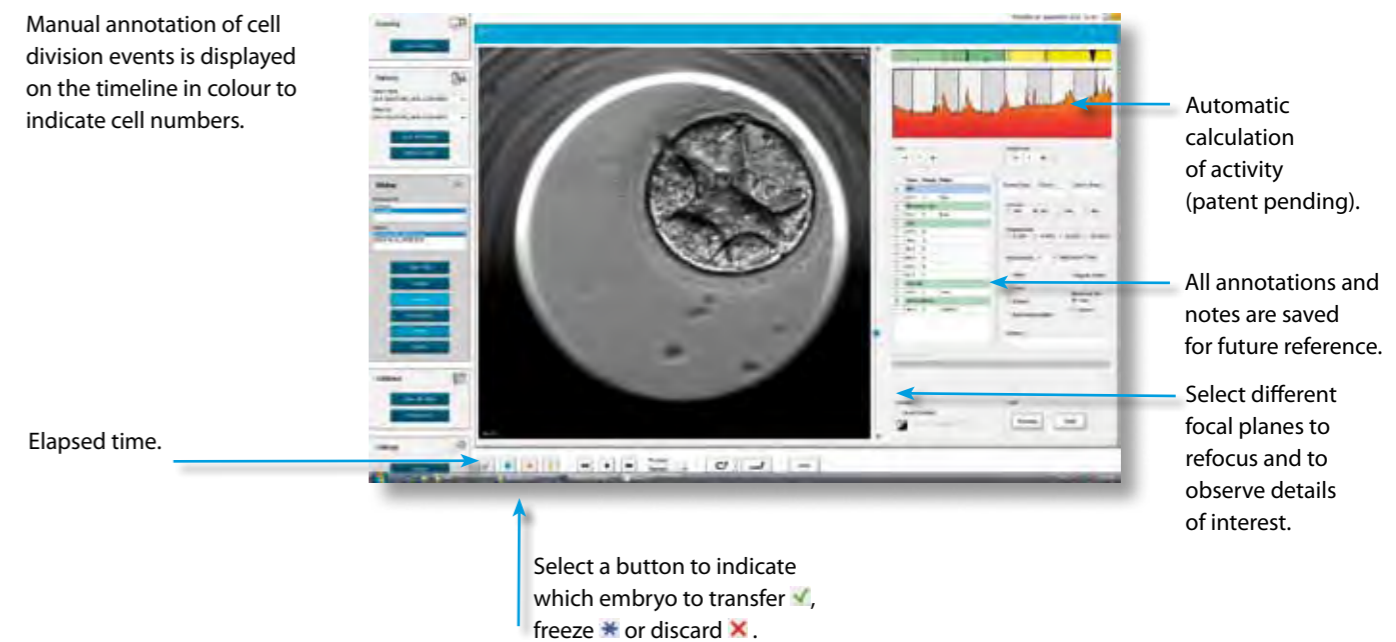


Annotate view allows synchronized time-lapse comparison of up to 3 embryos

Manual annotation of embryos

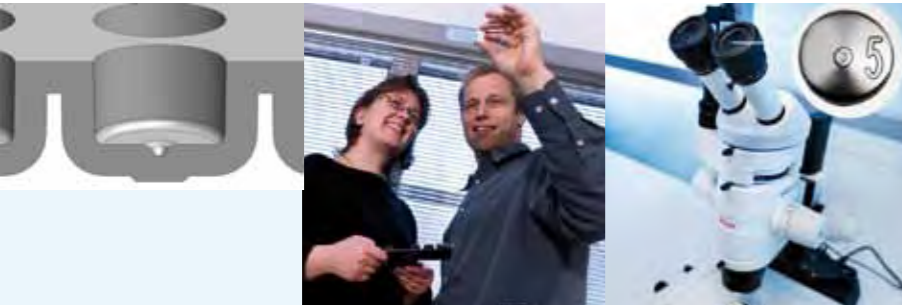
– for ease of reference

Manual annotation of cell division events is displayed on the timeline in colour to indicate cell numbers.



EmbryoSlide® Culture Dish

Safe and secure embryo handling



UNIQUE IDENTIFICATION OF EACH EMBRYO

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

SAFE AND EASY HANDLING

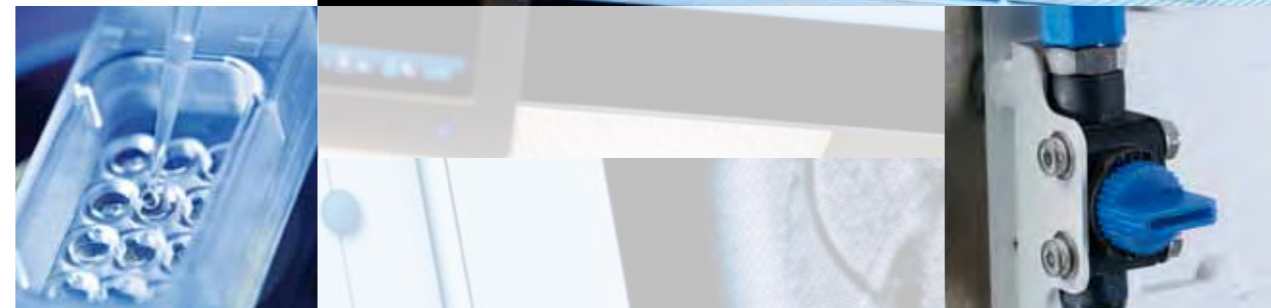
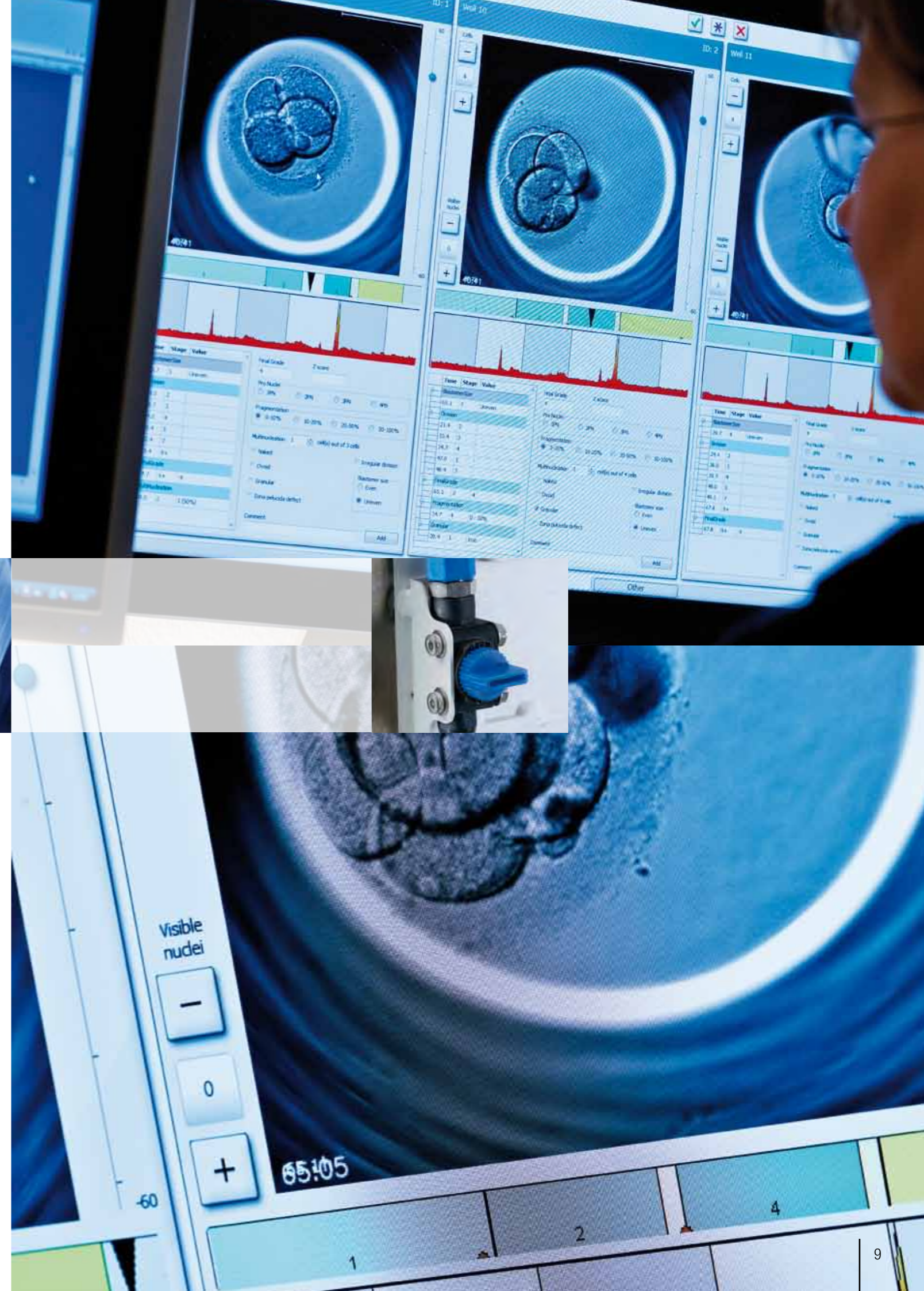
- Embryo settles to the bottom of the well. Conical sides of the well automatically place the embryo in a central depression with a diameter of 0.2 mm for direct thermal contact with a heated tray holder (patent pending)
- Vertical "tail-fin" ensures a firm grip and safe handling (patent pending)
- Separate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

COMPATIBLE WITH STANDARD MICROSCOPY

- Standard slide format
- Optical grade polymer optimized for microscopy

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



Specifications: EmbryoScope™ Time-lapse System

INSTRUMENT

Capacity	Embryo Monitoring System with time-lapse image capture
Operation	Six disposable EmbryoSlide® culture dishes holding 12 embryos each
Size	Individual slides may be inserted and removed independently
Weight	W × D × H (60.3 × 56.0 × 43.5) cm / (23.7 × 22 × 17.2) in
Power	60 kg / 121 lbs
Power Consumption	110-240V AC
Operating range	120W
	20 °C - 30 °C

IMAGE ACQUISITION

Focal planes	Select 3 to 17 focal planes at each timepoint in user defined vertical increments Allowed number of focal planes is dependent on selected cycle time.
Built-in microscope	Leica 20x, 0.40 LWD Hoffman Modulation contrast objective specialized for 635 nm illumination
Camera Resolution	1280 × 1024 pixels, 3 pixels per μm, monochrome, 8-bit
Embryo Illumination for image acquisition	≤ 0.04s per image using single red LED (635nm) gives 34μW cm ⁻²
Time between acquisitions	20 min cycle time for six slides, 5 min cycle possible with single slide

TRI-GAS INCUBATOR

Temperature	Integrated in instrument 30 °C to 45 °C ± 0.2°C* * Incubation temperature must be at least 7°C above ambient temperature.
Oxygen	5 % to 20 % ± 0.3%
CO ₂	2 % to 10 % ± 0.2 %
Active air circulation	Full purification of gas volume every 10 minutes
Volatile organic compounds	Removed by Whatman Carbon Cap™ active carbon filter
Particles	Removed by HEPA filter which retains 99.97 % particles >0.3 μm

INCUBATOR CONTROL

Data acquisition	Independent failure-proof embedded system controls vital function
Network	Intel Core duo T2300E 1.66 Ghz 2 Gb ram, fanless embedded PC
Operating system	100 Mb Ethernet
Data exchange	Microsoft Vista Pro®
Data format for images	Ethernet and front port for USB connection
Monitor	JPEG
Safety	12.1" embedded touch screen Continuous internal system integrity check for separate subsystems of the instrument as an added safety feature. USA-FDA 510(k) clearance to day 3 culture.



EmbryoViewer™ Workstation

Minimal configuration for hardware:

MAC PRO AND LED CINEMA DISPLAY 24"

One 2.66GHz Quad-Core Intel Xeon 3GB RAM
640GB 7200-rpm Serial ATA 3Gb/s
1TB 7200-rpm Serial ATA 3Gb/s
NVIDIA GeForce GT 120 512MB
One 18x SuperDrive
LED screen with 1920 X 1200 px resolution

ELECTRICAL AND OPERATING REQUIREMENTS

Input voltage:	100V to 240V AC; 50-60Hz
Maximum power:	212W
Energy saver mode:	1W or less

DIMENSIONS MACPRO

Height:	20.1 in (51.1 cm)
Width:	8.1 in (20.6 cm)
Depth:	18.7 in (47.5 cm)
Weight:	39.9 pounds (18.1 kg)

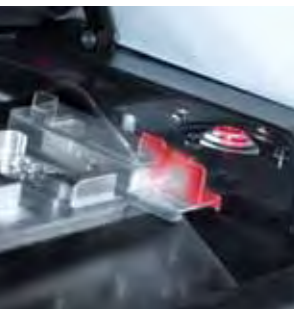
Dimensions LED Cinema display

Height:	18.8 in (47.8 cm)
Width:	22.5 in (57.3 cm)
Depth:	7.7 in (19.7 cm)
Weight:	21 pounds (9.5 kg)

INCLUDES A SCROLL WHEEL FOR EASE OF VIDEO REPLAY.

EmbryoViewer™ Software

Windows Vista Platform
Automatic remote backup to network disk can be enabled
Data storage data for up to 3000 IVF treatments
Patient and annotation data can be exported to Excel format for further data processing
Images can be exported as jpegs or AVI video files



Specifications EmbryoSlide® Culture Dish

- 12 numbered wells for incubation of individual embryos in droplets with 25 µl media
- Separate compartments for embryo and media, under a common oil reservoir
- Fully compatible with standard and inverted microscopes
- Standard slide format (25 × 75 mm)
- Single use, sterile
- Dust free packing in TYVEK pouches
- No need for humidified environment
- E-beam sterilized according to ISO 11137 with SAL 10⁻⁶
- Embryotoxicity tested with 1-cell mouse embryos – minimum 80% expanded blastocysts after 96 hrs
- Cytotoxicity test according to ISO 10993-5
- Europe: CE-marked
- USA-FDA 510(k) clearance
- Non-pyrogenic



- EmbryoScope, EmbryoViewer and EmbryoSlide are trademarks of Unisense FertiliTech A/S
- EmbryoViewer™ software not available for purchase in the USA pending FDA 510(k) clearance



CLASS IIA



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