Office of Director
INDIRA GANDHI INSTITUTE OF MEDICAL SCIENCES,
SHEIKHPURA, PATNA – 800 14 (Bihar, India)
Tel.: 0612 – 2297631, 2297099; Fax: 0612 – 2297225; Website: www.igims.org;
E-Mail: director@igims.org

Ref. No.: IGIMS / 2022/ 12 / Adm. / Store

Date: 07 / 01/ 2022.

NOTICE

Sub:- Purchase of "Embryo Scope Plus Time Lapse System" for the department of Reproductive Medicine at IGIMS- Patna on Proprietary basis Inviting Comments Thereon.

The Institute is in process to purchase of following item:-

1. "Embryo Scope Plus Time Lapse System; Make: Vitrolife - Denmark" for the department of Reproductive Medicine at IGIMS- Patna from M/s. Vision Diagnostic (India) Pvt. Ltd. - Delhi.

"Embryo Scope Plus Time Lapse System; Make: Vitrolife - Denmark" is Proprietary Item as stated by the said firm.

The above item and documents are being uploaded for open information to submit objection comments, if any, from any manufacturer regarding proprietary nature of the equipment/item. The comment should be received by office of the store, I.G.I.M.S., Sheikhpura - Patna (Bihar) on or before 21/ 01/ 2022 failing which it will be presumed that any other vendor is having no comments/objection to offer and case.

6/1/22

Director,
I.G.I.M.S. -Patna

TECHNICAL SPECIFICATION OF EMBRYO SCOPE PLUS TIME LAPSE SYSTEM

- Time lapse Enabled Assessment.
- It should have continuous surveillance of all embryos and flexible work routines.
- It should have facility for Digitized documentation and retrospective date analysis.
- Patient slide loading area isolated from remainder of incubation chamber.
- Incubation of other slides not affected by opening and closing of chamber
- Undisturbed culture in a stable environment.
- Modular system with Time Lapse and in built Tri gas Incubator for fast and accurate regulation of CO2 and O2 concentrations with minimal gas consumption.
- Full purification of gas volume every 6 minutes.
- Unique temperature control by direct heat transfer to individual media filled wells. Temperature is virtually unchanged by opening chamber (<0.2° C temperature recovery <1 minutes. When adding or removing patient sample.
- In Build Air purified by active carbon and HEPA filter. Removes VOCs and retains 99.97% of particles larger than 0.3µm.
- 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.
- Fully automated detection and focusing of up to 240 embryos 15 patients culture dishes with 16 embryos in each dish at one time.
- Culture dish used embryo toxicity tested with 1-cell mouse embryos, minimum 80% expanded blastocysts after 96 hrs. Cytotoxic test according to ISO 10993-5. Non-pyrogenic.
- MEA tested bar code labels for automatic patient registration.
- Image acquisition in multiple focal planes of all embryos, it should have 11 different focal planes or more.
- High quality Hoffman modulation contrast optics allows observation of key morphological features.
- It should have special optics for red light at 630 nm to eliminate high energy light exposure.
- Knowledge building for improved embryo selection.
- Intuitive annotation and Decision support tools.
- Should have both morphological and morphokinetic observations to select the best embryo.
- It should have unique software for annotate and compare development of selected embryos from data acquired by time lapse incubator. Instrument running conditions are automatically assurance.
- It should have facility for Automatically calculated cellular activity indicating cell division events.
- System should comes with known Implantation Date (KID) score software, which helps into morphokinetic traits associated with the implantation potential of embryos transferred on day. The model should be designed to help us to avoid transferring embryos with low implantation potential.
- It should be based on water impermeable polymer slide and cover of immersion oil prevent dehydration during handling in low humidity laboratory air and in dry incubators.
- System should come with complete software and hardware including dedicated server for remote access facility. System should have feature of iPad counselling app to show patient their own embryos at any point of time.
- It should have facility to observe and assess patient embryos from our reporting room via Time Lapse server and instantly access current patient date for assessment.
- System should have facility for unique identification of each embryo to avoid any error.
- onsite technical support and training of embryologist and clinicians of the unit.
- Compatible USB port, CD.
- Printer to print the embryo picture cables/wireless. (glossy post card size)
- Storage/ memory.
- Systems should have US FDA 510(k) clearance of clinical use.
- System should have Custom defined variables, Algorithm development, and Model building software.
- It should have Input of advanced evaluation models to automatically rank embryo score using "Compare and Select" options.
- System should have Morphokinetic decision support tool for day 3 and day 5 transfer based on large pregnancy outcome database.
- System should have Guided annotation based on blastomere activity, Customized Annotation tool and Drawing tools to measure embryo features (Zona, diameter).
- System should be Clinically validated and it should have more the 300 Abstracts & publications linking morphokinetics to implantation using time--lapse system.
- System should comes with Five year warranty and five year CAMC.

- To improve workflow, the EmbryoSlide+ culture dishes are automatically registered using a special patient barcode labelling system. With the small footprint you will make efficient use of space, a valued asset in all labs and especially where space is limited. The large capacity in combination with a small footprint and efficient workflow provides optimised usage of clinic resources. A patient identification barcode system offers a flexible and efficient workflow. EmbryoScope+ automatically reads and registers entry of a new patient and re-entry of an existing patient dish.
- EmbryoScope+ is a state-of-the-art technology that enables a stable culture environment for embryos. Temperature is tightly regulated by direct heat contact and air is continuously purified through a HEPA/VOC filter. An integrated gas mixer allows the implementation of reduced oxygen conditions easily and economically. Small incubation chambers allow rapid recovery of culture conditions after door opening.
- When introducing EmbryoScope+ to your IVF laboratory, you are guaranteed a digital transformation in the workflow. With the ES server, you can access the time-lapse data from all connected EmbryoScope+ incubators. Moreover, it is possible to view the data from multiple EmbryoViewer workstations. These can be placed in the IVF laboratory or in your office, and you can even access the data stored on the server from another clinic or another remote location using a secure connection. This enables you and your colleagues to view, annotate and select embryos with geographical flexibility.
- Electronic Medical Record integration EmbryoScope+ can be integrated with all compatible EMR systems.
- With EmbryoViewer software, you can achieve improved selection, or de-selection, of embryos by a combination of discovering both morphological and morphokinetic parameters. Important parameters such as the dynamic morphology, critical cleavage patterns and morphokinetics can only be observed with time-lapse technology.
- With EmbryoViewer software, you also have the possibility to set up one or more models according to clinic specific criteria and rank embryos accordingly using the Compare & Select feature. With the possibility to define selection, deselection or information criteria and even user defined variables, you can create customised models with criteria fitting your own clinical data.

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Vitrolife

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To,
The Director
Indira Gandhi Institute of Medical Sciences
Bailey Rd, Raja Bazar, Sheikhpura,
Patna, Bihar 800014

November 12, 2021

Subject: Proprietary Certificate of EmbryoScope

Dear Sir,

We the undersigned, Vitrolife Sweden AB, Reg. No. 556546-6298, located at Gustaf Werners gata 2, Box 9080, SE-400 92 Göteborg, Sweden, herewith certifies that the EmbryoscopeTM + time-lapse system and its accessory equipment having the following Part Numbers, are manufactured by Vitrolife A/S, Denmark.

- EmbryoScope+ EU 220V
- ES+ server hardware EU
- ES+ server software
- EmbryoViewer+ hardware EU
- EmbryoViewer+ software
- ES+ EmbryoSlide (40 x 1 units/pack)
- Label printer for EmbryoScope+
- Resin foil for label printer (last app. 3 years)
- Label for ES+ Slide (1000 labels)
- KIDScore D3 & D5 package
- Guided Annotation

TRUE COPY ATTESTED
O.P. SINGH
Advocate
Regd. No. 1980
Notary Public
Ghaziabad
26 NOV 2021

This equipment has following proprietary/unique features:

1. Fully automated detection and focusing of up to 240 embryos from 15 patients' culture dishes with up to 16 embryos in each dish at one time.
2. Image acquisition in multiple focal planes of all embryos, with up to 11 different focal planes.
3. Both morphological and morphokinetic observations to select the best embryo and having unique software for annotating and comparing development of selected embryos from data acquired by time-lapse incubator. Instrument running conditions are monitored automatically.
4. Known Implantation Date (KID) score software, which helps interpret morphokinetic traits associated with the implantation potential of embryos transferred on day 3 or day 5. The model should be designed to help us to avoid transferring embryos with low implantation potential.
5. Facility to observe and assess patient embryos from our reporting room via the time-lapse server and instantly access current patient data for assessment, and has custom defined variables, algorithm development, and model building software.
6. Advanced evaluation models to automatically rank embryo score using "Compare and Select" options and Morphokinetic decision support tool for day 3 and day 5 transfer based on large implantation outcome database.

Vitrolife

Vitrolife Sweden AB | Org nr 556546-6298
Box 9080 | 400 92 Göteborg
Besöksadress: Gustaf Werners gata 2
421 32 Västra Frölunda

Tel 031 721 80 00
Fax 031 721 80 99
www.vitrolife.com

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7. Automatically calculated cellular activity indicating cell division events, and facility for Guided annotation based on blastomere activity, Customized Annotation tool and Drawing tools to measure embryo features (Zona, diameter).

No other companies or firms are having similar equipment worldwide with specifications described above. If you need any further information, please feel free to contact us.

Sincerely Yours,

Meishan Jin, PhD
Vice President Market Region Asia
Vitrolife Sweden AB
Tel: +46 31 721 8040 (office)
Fax: +46 31 721 8090
E-mail: mjin@vitrolife.com
Website: www.vitrolife.com

Vitrolife
Box 9080, SE-400 92 GÖTEBORG
Tel +46-31-721 80 00
Fax +46 31-721 80 90
Sweden

TRUE COPY ATTESTED

O.P. SINGH
Advocate
Regd. No.-1680
Notary Public
Ghaziabad

26 NOV 2021

TECHNICAL SPECIFICATION OF EMBRYO SCOPE PLUS TIME LAPSE SYSTEM

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Shubhangi Kumari 26/11/21

Bhavana 26/11/21

26/11/21

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