

ES server User manual



Caution: Federal law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.

ES server, software version 7.9

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1 Introduction

The manual describes the basics of the ES server. To benefit from the manual, you need a basic understanding of how the CulturePro system and/or the EmbryoScope time-lapse system (version D, +, Flex or 8) work and advanced knowledge about IT in general and network set-ups in particular.

The ES server allows users to update and view common data within clinics. This is achieved by setting up a client-server network. The server acts as the central unit that stores data and controls the data flow to and from the connected devices. The server can be connected to a number of CulturePro incubators, EmbryoScope time-lapse incubators (version D, +, Flex or 8), computers with the EmbryoViewer software installed and mobile solutions. For further information on which devices can be connected, see section 3.

The ES server is a class I medical device that conforms to the requirements of the Medical Device Regulation (EU) 2017/745.

1.1 Intended use

The ES server is a software package intended to be used together with an incubator as part of fertility treatment.

1.2 Indications for use

The ES server software is intended to store, archive and transfer data. In addition, this software includes functions for managing models and performing calculations based on image data and embryo development parameters.

The KIDScore D3 tool is an optional tool that can be used in conjunction with the ES server and the EmbryoViewer software. The KIDScore D3 tool provides decision support for prediction of the likelihood of embryos developing to the blastocyst stage by scoring them according to their statistical viability. Adjunctive information provided by KIDScore D3 aids in the selection of embryo(s) for either transfer on day 3, freezing or continued embryo development when, following morphological assessment on day 3, there are multiple embryos deemed suitable for transfer or freezing. The KIDScore D3 tool is only to be used with the EmbryoScope time-lapse incubator system.

1.3 Intended users

The primary intended users of the ES server are system administrators at IVF clinics.

1.4 Clinical benefit

As an accessory to a medical device, the ES server software provides the indirect clinical benefit of enabling use of software and incubator(s) connected to the system, thereby supporting:

- Improved implantation/pregnancy rate
- Reduced pregnancy loss rate.

1.5 Conventions used in this manual

RESTRICTIONS ON USE: Functions or actions restricted to certain identified persons or purposes or regulatory restrictions that **MUST** be observed when operating the ES server.

WARNINGS: Conditions or actions that – if the instructions are ignored – may potentially result in erroneous data or non-recoverable loss of data.

CAUTIONS: Important information needed before or during the use of the ES server.

NOTES: Explanations or additional information provided for the purpose of clarification.

1.6 Proposed workarounds

For details about any known anomalies and limitations in the software as well as proposed workarounds, please refer to the separate handout on this subject provided by Vitrolife.

1.7 Important restrictions and warnings

The following restrictions and warnings will ensure the correct use of the ES server by qualified clinic personnel. Users must be qualified to operate the server and qualified to perform procedures associated with server use in accordance with local qualification standards.

All administrators of the server must agree to read and understand this user manual, observe the restrictions regarding use and read the following warnings.

Users should contact Vitrolife immediately to report any incident and/or injury to a patient, operator or maintenance employee that occurred as a direct or indirect result of operating the ES server software and associated hardware. Any serious incident that has occurred in relation to the server should be reported to the competent authority of the Member State in which the user is established.

RESTRICTIONS ON USE
Access to the server must be controlled so that only qualified and trained personnel are permitted access. Untrained personnel could inadvertently change the configuration or the license file, so it is essential that the server is installed in a secure place not accessible by patients or the public.

WARNING
It is the responsibility of the clinic to set up backups of image and patient data to a safe external hard disk.

WARNING

- Data transmitted between the server and connected devices should always be guarded against unauthorized access. Local legislation and security policies may require the clinic to protect transmitted data in specific ways such as through strong encryption. The clinic is solely responsible for safeguarding transmitted data against unauthorized access and for securing compliance with local legislation and security policies when transmitting data.

WARNING

- The server must only be installed by a person certified by Vitrolife. It must not be re-installed by the clinic IT department, nor by any other users, except if specifically instructed to do so by Vitrolife and then only under the strict supervision and guidance of a person certified by Vitrolife.
- The computer on which the server is installed must remain at the location where it was set up by a person certified by Vitrolife and may only be moved by such certified person or upon express written authorization.

WARNING

- The server will be configured during installation by a person certified by Vitrolife.
- Making changes to the configuration of the server may cause the server to not function properly, and the server may become vulnerable to external intrusion.

WARNING

- When the server has been installed, do NOT change neither the instrument number nor the computer name of any device connected to the server. Doing so may cause irrecoverable loss of data.

1.8 General cybersecurity recommendations

Users are advised and expected to take the following measures to reduce cybersecurity risk in order to ensure that the device will work as designed in the intended user environment:

- Ensure that personnel are properly trained in cybersecurity awareness
- Prevent physical access to the equipment by unauthorized users
- Use strong passwords (at least eight characters including both uppercase and lowercase letters, numbers and at least one special character).

Users must inform Vitrolife A/S without any undue delay upon becoming aware of a cybersecurity vulnerability incident or any suspected security events.

For details about how to reduce cybersecurity risk, please refer to the separate guide on this subject provided by Vitrolife.

2 Hardware requirements

The ES server must be installed on a computer with the below minimum requirements depending on the configuration of the server. See section 3.3 for a specification of the various configurations.

- Computer with Microsoft Windows installed
- Quad-core 3 GHz processor
- 8 GB RAM
- 2 Gb LAN connections
- 240 GB hard disk for OS and software
- Hard disk capacity for data storage depending on the configuration specified in section 3.3
- Compliance with the requirements of the IEC 61010-1 and IEC 61326 (or equivalent) standards.

3 Devices connected to the ES server

The ES server acts as a central unit that stores data and controls the data flow between various connected devices. All connected devices can access the same data on the server. Users can either edit or view the data as allowed by their user privileges (set up in the EmbryoViewer software). When the server is installed in the clinic, all users of the EmbryoViewer software must log in during start-up.

3.1 Types of connected devices

The following devices can be connected to the ES server:

- Computers on which the EmbryoViewer software and/or Vitrolife Technology Hub is installed
- CulturePro incubators
- EmbryoScope time-lapse incubators (version D, +, Flex or 8).

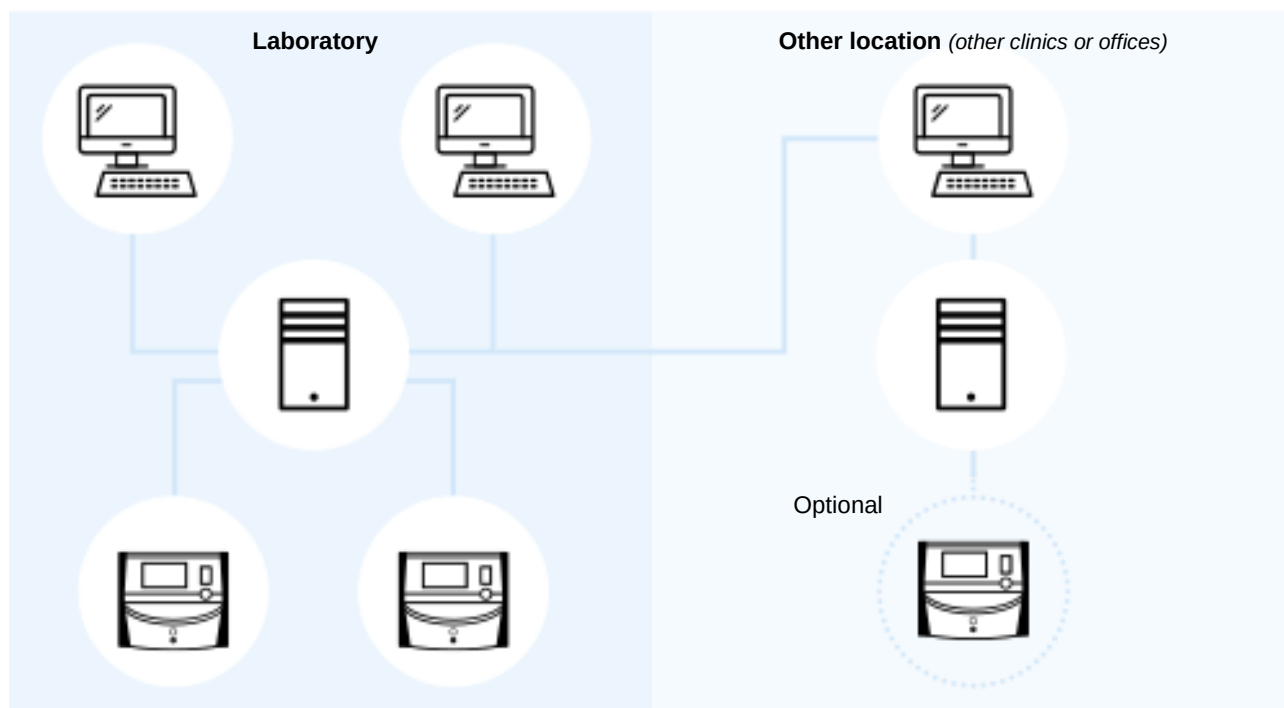


Figure 1: Devices connected to the ES server

3.2 Remote server connection

Users of the EmbryoViewer software can select an ES server positioned in a remote office or clinic during login. This allows the user to view and change data in a remote clinic (depending on user rights).

Users can connect to a server in a remote location when the following requirements have been fulfilled:

- The EmbryoViewer software has been configured by Vitrolife for more than one server.
- A secure remote connection has been established between the locations.
- The user actively selects the remote server when logging on to the EmbryoViewer software.

NOTE

- Servers cannot communicate with each other and thereby allow a common pool of data to be shared between users.
- The EmbryoViewer software can only be logged on to one server at a time and thereby access the data on that specific server.

The connected devices can communicate with each other as illustrated by the following:

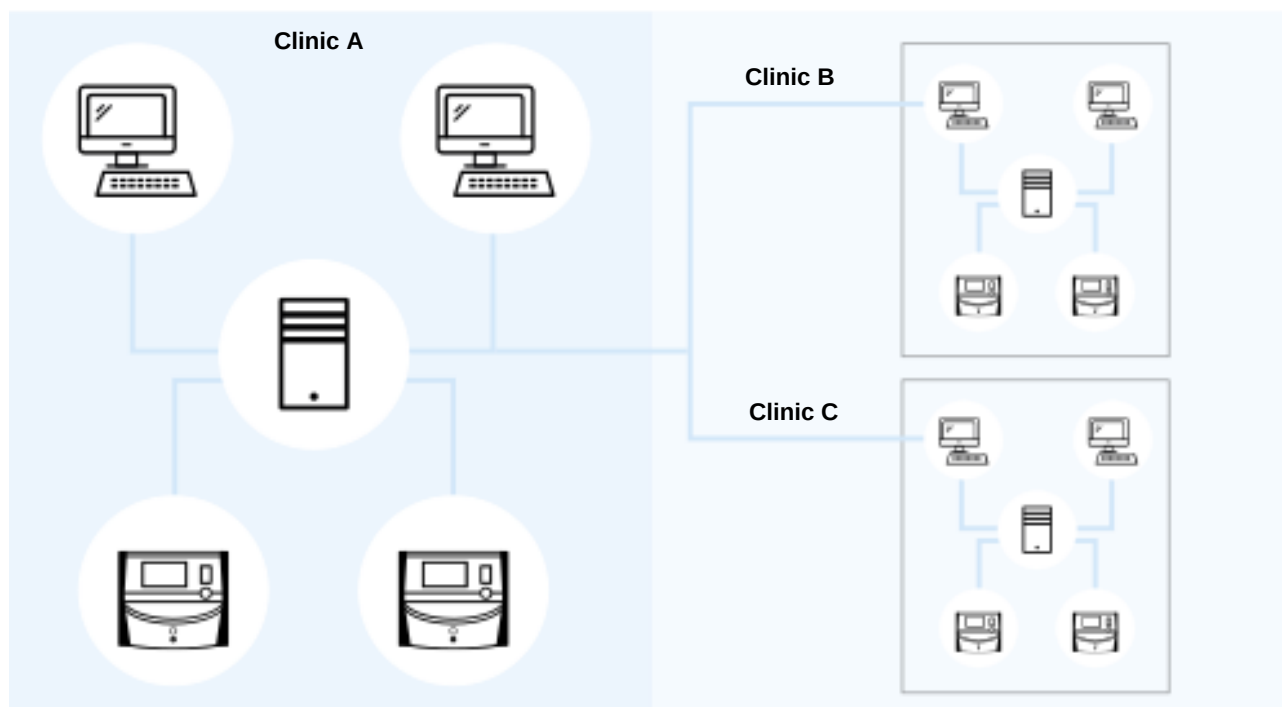


Figure 2: Set-up with more than one ES server

In figure 2, three different servers are installed in a chain of clinics, one in each clinic.

If the EmbryoViewer software has been configured to communicate with a server in one location, it cannot automatically communicate with a server in another location.

If you need a computer to communicate with a different or an additional server, the configuration file in the EmbryoViewer software needs to be changed. For further information on the configuration file in the EmbryoViewer software, see section 6.

Irrespective of the configuration, each computer can only communicate with one server at a time (see figure 3). When logging into the EmbryoViewer software, the user must select which server to log on to.

In the next example, one of the computers that run the EmbryoViewer software in Clinic B has been logged on to the server in Clinic A. In this case, the user in Clinic B cannot access the data on the server that is also installed in Clinic B.

In this set-up, the dimmed parts in figure 3 will be inaccessible to the user:

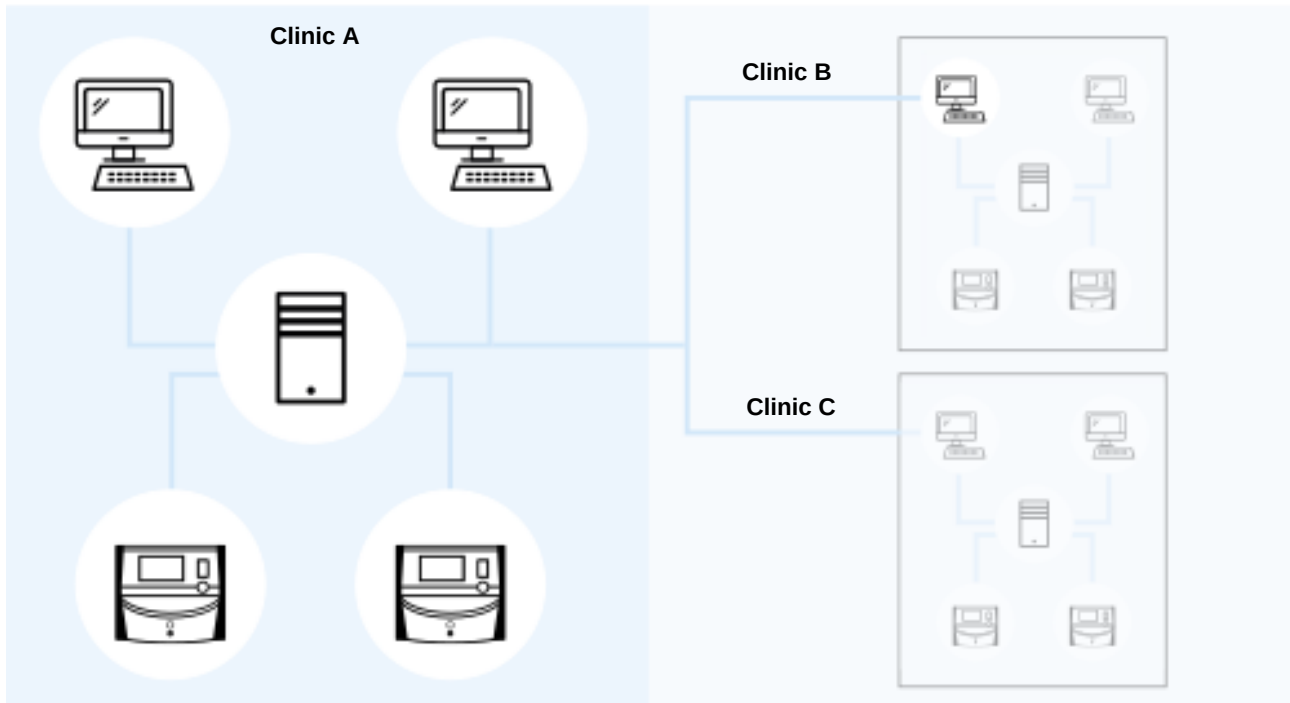


Figure 3: EmbryoViewer software in Clinic B connected to ES server in Clinic A

3.3 Number of connected devices and server response time

Two different server configurations exist. The configurations are software-based. The maximum number of devices that can be connected to the server depends on the acquired configuration.

3.3.1 Configuration 1 – basic

- 1 computer with the EmbryoViewer software and/or Vitrolife Technology Hub installed
- 1 EmbryoScope+/Flex OR
2 CulturePro/EmbryoScope version D/EmbryoScope 8.

This configuration is compatible with the ES server, ES server+, VTH server and VTH server+ hardware configurations.

3.3.2 Configuration 2 – high capacity

- 4 computers with the EmbryoViewer software and/or Vitrolife Technology Hub installed
- 16 CulturePro/EmbryoScope version D/EmbryoScope 8 OR
14 CulturePro/EmbryoScope version D/EmbryoScope 8 and 1 EmbryoScope+/Flex OR
12 CulturePro/EmbryoScope version D/EmbryoScope 8 and 2 EmbryoScope+/Flex OR
10 CulturePro/EmbryoScope version D/EmbryoScope 8 and 3 EmbryoScope+/Flex OR
8 CulturePro/EmbryoScope version D/EmbryoScope 8 and 4 EmbryoScope+/Flex OR
6 CulturePro/EmbryoScope version D/EmbryoScope 8 and 5 EmbryoScope+/Flex OR
4 CulturePro/EmbryoScope version D/EmbryoScope 8 and 6 EmbryoScope+/Flex OR
2 CulturePro/EmbryoScope version D/EmbryoScope 8 and 7 EmbryoScope+/Flex OR
8 EmbryoScope+/Flex.

This configuration is compatible with the ES server+ and VTH server+ hardware configurations.

You are strongly advised not to connect more devices than specified as server performance may suffer. This means that the server may be slow to respond to requests. Vitrolife does not guarantee normal operation if you connect more devices than specified.

4 Server infrastructure

The ES server uses a variety of network ports and protocols to communicate with the client computer, incubators and other connected devices. While dedicated firewalls and filters can be used to help secure your network, if these technologies are configured to block ports and protocols that are used by the server, the server may not be able to respond to legitimate requests. If the server is unable to respond to legitimate client requests, it may not function properly or at all.

The following sections provide a short description of each service and interface in the server set-up, including (whenever relevant) the name and location of the interface/service, and display the ports and the protocols required by each of them.

4.1 ES server software

The ES server software runs as a service. The server functions as the central unit of communication and controls the data flow to and from all connected devices. The service also stores the data created or updated from these connected devices.

NAME OF SERVICE	LOCATION	PORT	PROTOCOL	NETWORK CARD
EmbryoServer	N/A	N/A	N/A	N/A

To start/stop the service, go to **Computer Management -> Services and Applications -> Services**. Select **EmbryoServer**, and click the **Actions** toolbar -> **Start/Stop**.

4.2 Instrument Monitoring Client

The Instrument Monitoring Client consists of two services that transmit technical instrument data from the clinic to a Vitrolife server:

Vitrolife IMS Data Service: Receives data from the incubators connected to the ES server.

Vitrolife IMS Client Service: Transmits the data received from the Vitrolife IMS Data Service to a Vitrolife server.

Only technical data such as the number of culture dishes in the incubator, temperature, gas consumption, used space on the hard disk, etc. are uploaded to Vitrolife. No patient data will be uploaded by the IMS services. The purpose of transmitting the data is to provide the service technician with operational data and thereby optimize the technician's service visit at your clinic.

Data from the IMS services are sent to Vitrolife on a continuous basis. The services need a data connection with an upload speed of > 0.5 Mbps per incubator installed in your clinic. This means that if you have two incubators, the upload speed of your data connection must be > 1 Mbps. Your firewall should allow the Instrument Monitoring Client to run uninterruptedly and on a stable connection.

The Vitrolife IMS Data Service creates a queue of the data received from connected incubators. In case the service is interrupted, it will continue receiving data from the incubators from the time when the service is re-started.

If the Vitrolife IMS Client Service is interrupted, it will continue sending all of the data waiting in the queue when re-started.

NAME OF SERVICE	LOCATION	PORT	PROTOCOL	NETWORK CARD
Vitrolife IMS Data Service	N/A	N/A	N/A	N/A
Vitrolife IMS Client Service	N/A	80	Http	No. 1

To start/stop the service, go to **Computer Management -> Services and Applications -> Services**. Select **Vitrolife IMS Data Service/Vitrolife IMS Client Service**, and click the **Actions** toolbar -> **Start/Stop**.

4.3 Backup service

WARNING

- It is the sole responsibility of the clinic to set up backups of image and patient data to a safe external hard disk. The clinic may decide to use either a backup program integrated in the Windows operating system, a script or an external backup tool.

The ES server does not integrate any facilities to automatically back up and safeguard your data. It is the sole responsibility of the clinic to ensure that all data are stored safely and to choose a program that will perform scheduled data backups. Therefore, you should install a suitable backup program on the server.

In addition to selecting a program that will accommodate your needs, you also need to decide how often you want to back up your data. You are advised to perform a daily backup.

NAME OF SERVICE	LOCATION	PORT	PROTOCOL	NETWORK CARD
The clinic will select a suitable program	N/A	N/A	N/A	N/A

4.4 Web interface

The web interface supports communication between web-based applications and the ES server. The web interface is e.g. used when new licenses are uploaded to the server.

NAME OF INTERFACE	LOCATION	PORT	PROTOCOL	NETWORK CARD
N/A	N/A	4010	Http	No. 1

4.5 Interface to computers with EmbryoViewer software

The interface to the computers that run the EmbryoViewer software delivers data requested from the connected computers and receives new and updated data from these computers. When new or updated data are received from the computers, the server stores them in the central database and allows them to be shared by other users who have a license for that particular server.

Transactions are done in real time: as soon as data are added, updated or deleted and saved in the EmbryoViewer software, the server database will be updated.

NAME OF INTERFACE	LOCATION	PORT	PROTOCOL	NETWORK CARD
N/A	N/A	3010	Proprietary	No. 1

4.6 Interface to incubators

The interface to the incubators delivers data requested from the connected incubators and also receives new and updated data from them. When new or updated data are received from the incubators, the server stores them in the central database and allows them to be shared by other users.

Transactions are done in real time: as soon as data are added, updated or deleted and saved on the incubator, the server database will be updated.

The incubators will use a separate network card as they need special care and protection. They do not run with any antivirus programs etc., and they should therefore not be able to connect to the internet.

NAME OF INTERFACE	LOCATION	PORT	PROTOCOL	NETWORK CARD
N/A	N/A	3000	Proprietary	No. 2

4.7 Interface to external systems (e.g. EMR integration)

The interface to external systems is a public API that allows integration between the EmbryoViewer software and external systems, e.g. the clinic EMR system. The provider of the external system must have prepared it to integrate with this API for the interface to function as intended.

The interface delivers data to connected systems and receives new and updated data from these systems. When new or updated data are received from the external systems, the data are stored in the central database and can be shared with users of the EmbryoViewer software.

Transactions are done in real time: as soon as data are added, updated or deleted and saved, the server database will be updated.

NAME OF SERVICE	LOCATION	PORT	PROTOCOL	NETWORK CARD
Vitrolife ES Public API	N/A	4000	Https	No. 1

To start/stop the service, go to **Computer Management -> Services and Applications -> Services**. Select **Vitrolife ES Public API**, and click the **Actions** toolbar -> **Start/Stop**.

4.8 Graphical overview of server infrastructure

The following illustration provides an overview of the server infrastructure:

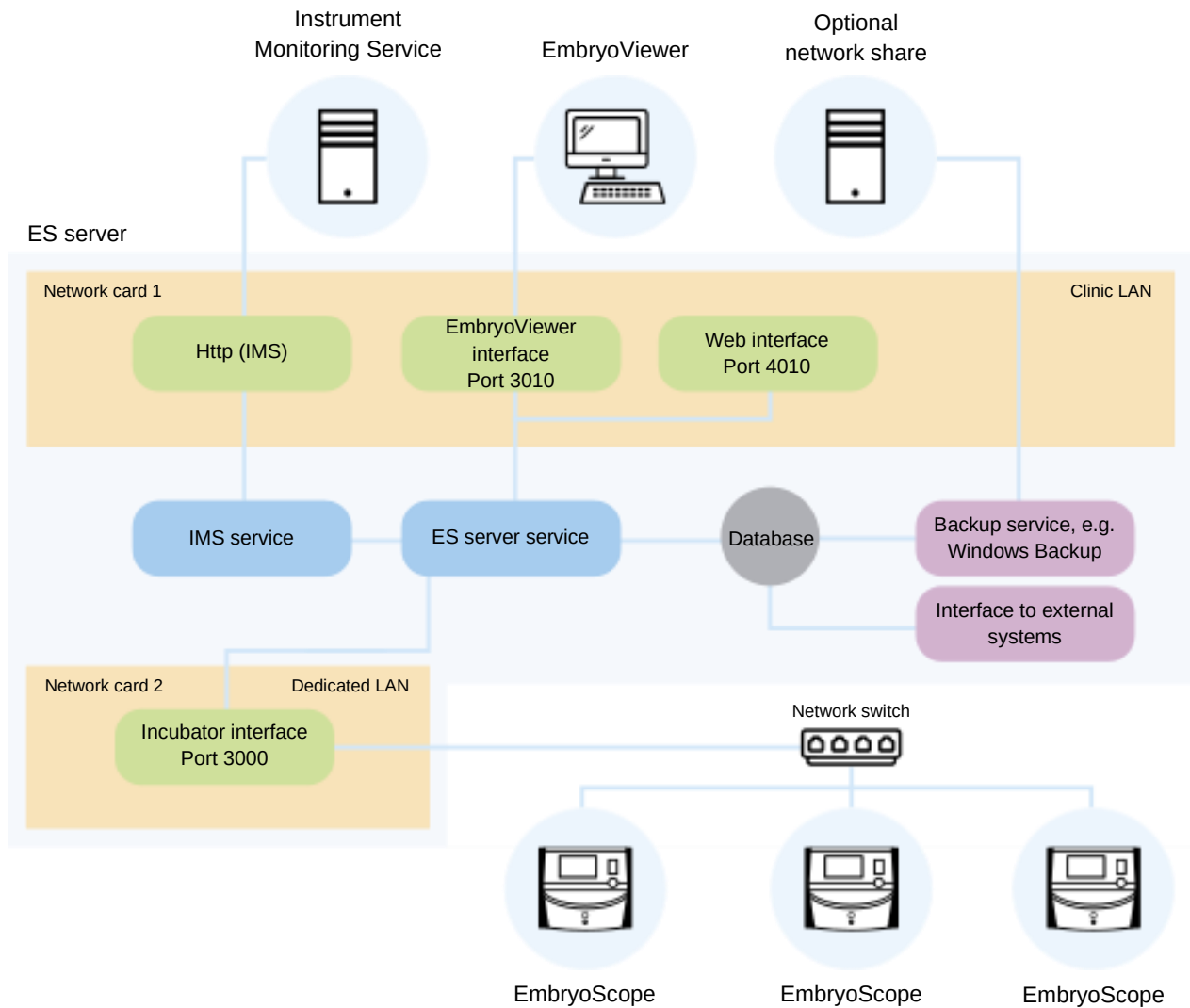


Figure 4: Server infrastructure

See alternative set-ups with either CulturePro, EmbryoScope version D, EmbryoScope+, EmbryoScope Flex or EmbryoScope 8 in section 3.3.

5 Licenses

In order to use the ES server, a license needs to be installed on the server for all computers that run the EmbryoViewer software and need access to the server.

When the server is first installed in your clinic by a person certified by Vitrolife, a license file will also be placed on the server. You may later need a new license file if:

- The file containing your licenses has been lost or damaged.
- The EmbryoViewer software on one of your computers needs to be able to access a different server or additional servers.

If you need a new license or experience any problems with the existing ones, please contact Vitrolife.

CAUTION
• Do NOT modify or delete the license file as this will invalidate your licenses and restrict your access to the server. In this case, the server will not allow access from any client computers or any mobile devices. The server can then only be accessed via a web browser from which a new license file can be installed. Contact the Vitrolife support team for assistance.

6 Configuring the EmbryoViewer software to communicate with a different server

WARNING
• The EmbryoViewer software will be configured during installation by a person certified by Vitrolife. • Making changes to the configuration of the software may cause the software to not function properly, and the server may become vulnerable to external intrusion.

The ES server as well as the EmbryoViewer software will be configured during installation. Usually, you should not make any changes to the configuration files.

However, you need to modify the configuration file for the EmbryoViewer software if you want a particular computer to communicate with a different server or with an additional server.

The configuration file is named Viewer_d.ini. The file is placed in the same directory as the Viewer_d.exe file.

The file contains only one section: [Servers]. It is from this file that the EmbryoViewer software reads the list of available servers. The file has the following format:

server name=ip_address:port number

The “ip_address” is the IP address of the server, and “port number” specifies which port the server uses for communication with the computer that runs the EmbryoViewer software.

The “server name” is the name that will appear in the **Database** field on the login screen of the EmbryoViewer software:



Figure 5: Login screen of the EmbryoViewer software

In the following example, an additional server is added to this configuration file:

```
[Servers]
LOCAL=192.168.0.10:3010
Clinic A ES server=192.168.1.10:3010
```

Insert a new line (red line below) in the configuration file to add an additional server:

```
[Servers]
LOCAL=192.168.0.10:3010
Clinic A ES server=192.168.1.10:3010
Clinic B ES server=192.167.1.10:3010
```

If the IP address of the server is changed, you will also need to change the IP address in this configuration file. Also, the IP address and port number specified in the Viewer_d.ini file must match the data in the ViewerTransport section of the EmbryoServer.ini file, which contains the server configuration.

NOTE

- If you modify the configuration file of the EmbryoViewer software to have a particular computer communicate with a different server, the license file on the server also needs to be updated. Contact the Vitrolife support team for assistance.

7 Connection failure between the ES server and the EmbryoViewer

In order to use the EmbryoViewer software, there must be a connection between the ES server and the EmbryoViewer software. If there is no connection, the software will display an error.

7.1 The server has not been started

If there is no connection to the ES server when you start the EmbryoViewer software, the program will display an error message:

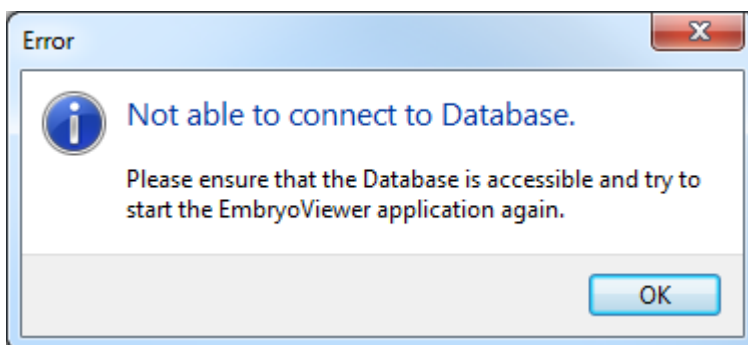


Figure 6: No connection to the EmbryoViewer software

The server is installed as a service. Therefore, if this error message is displayed, check that the EmbryoServer service is started:

Go to **Control Panel -> System and Security -> Administrative Tools -> Services**.

See section 4.1 for information about this service.

7.2 The connection to the ES server is lost while data are being edited

If the connection to the server is lost while you are editing data, the EmbryoViewer software will display the following message on the login screen:



Figure 7: “No connection” message on the login screen

The EmbryoViewer software will automatically attempt to re-establish the connection to the server. If this is not successful, follow the guidelines provided by the message:

- Check that the network cable is correctly plugged in.
- Check that the computer is connected to the network.
- Check that the computer on which the server is installed is switched on.
- Contact the Vitrolife support team.

When the connection to the server has been re-established, the following message will be displayed on the login screen:



Figure 8: “Connected to database” message on the login screen

You will now be able to log in and continue to view or edit the data.

If you were editing the data when the connection was lost, any changes made to the data in the EmbryoViewer software will still be available on the local computer when the connection is re-established. The data will, however, NOT be automatically saved. It is therefore necessary to manually save the data.

WARNING

- If the EmbryoViewer software was shut down while there was no connection to the server, the data will no longer be available in the local database. In this case, any unsaved data will be lost.

Likewise, any unsaved data in the incubator will still be available after the connection to the server has been lost, even if the software integrated in the incubator was shut down while there was no connection.

8 Symbols and labels

Label	Description	Note
	Declaration by the manufacturer that the device meets all of the applicable requirements in the Medical Device Regulation (EU) 2017/745	-
	Medical device	-
	Unique device identifier	-
	Manufacturer name and address	See section 10.

9 Disposal of waste

In order to minimize the waste of electrical and electronic equipment, waste must be disposed in accordance with the Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) as amended by Directive (EU) 2018/849. This includes: PCBs (lead-free HASL), switches, PC batteries, printed circuit boards and external electrical cables. All components are in accordance with the RoHS 2 Directive 2011/65/EU, which states that new electrical and electronic components do not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers.

10 Contact information

Urgently need help? Call our service hotline for support:

+45 7023 0500

(available 24 hours a day, 7 days a week)

E-mail support: support.embryoscope@vitrolife.com

(response within 2 working days)



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