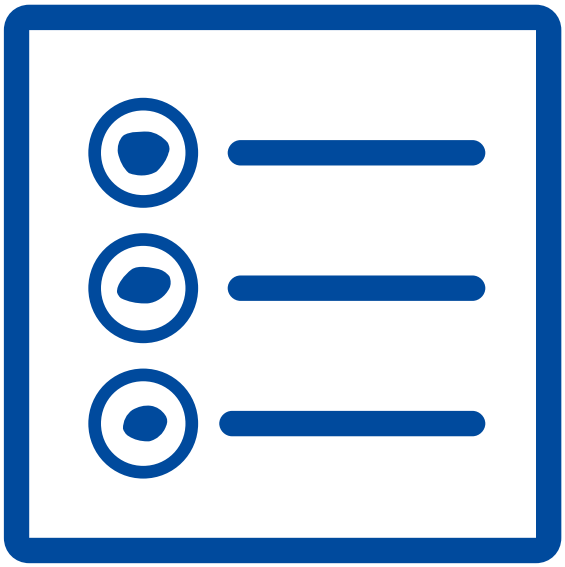
CohortView™

User manual



CohortView, version 1

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1 Introduction

This user manual provides information on how to use CohortView, which is designed to provide users with an overview of the embryo fate for all embryos in the system related to a patient with the option to reset an embryo fate decision.

In the user manual, all references to “EmbryoScope” cover both EmbryoScope+, EmbryoScope Flex and EmbryoScope 8 time-lapse incubators.

All screenshots in this user manual show the English version of the software. Translations are provided in the accompanying text where relevant.

1.1 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 using CohortView.

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

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

1.2 Important restrictions and cautions

All users of CohortView must agree to read and understand this user manual, observe the restrictions on use and read the following cautions.

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 device and associated hardware. Any serious incident that has occurred in relation to the device should be reported to the competent authority of the Member State in which the user is established.

RESTRICTIONS ON USE
• All rights in CohortView belong to Vitrolife A/S. Your installation and use of CohortView are subject to the terms of the end user licence agreement. • You may not copy, modify, decompile, reverse engineer, disassemble or convert CohortView or assign, transfer, sell, rent or lease CohortView to any third party.

CAUTION
• CohortView may not be used for any other purpose than intended and specified by Vitrolife A/S as such usage may result in incorrect decisions being made by the embryologist.

NOTE
• All names and treatment data presented in this manual are purely fictional.

1.3 General cyber security recommendations

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

- Ensure that personnel are properly trained in cyber security awareness
- Prevent physical access to the equipment by unauthorised 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 cyber security vulnerability incident or any suspected security events.

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

1.4 Purpose of CohortView

CohortView is designed to enable users to look up a patient and see all the patient's embryos and the decided embryo fate. The embryo fate decision can be made through a Vitrolife Technology Hub module such as iDAScore or through the EmbryoViewer software. CohortView provides users with a simpler workflow when an embryo fate decision needs to be changed.

CohortView does not offer any analysis or evaluation, but simply provides users with an overview.

1.5 Intended use

The intended use of CohortView is to provide users with an overview of the embryo fate for all embryos in the system related to a patient with the option to reset an embryo fate decision.

1.6 Intended users

Embryologists, other laboratory personnel and clinic staff at IVF clinics.

1.7 Proposed workarounds

There are currently no known anomalies and limitations in CohortView.

1.8 Requirements for using CohortView

To be able to use CohortView, you need:

- An EmbryoScope
- iDAScore or EmbryoViewer software
- Vitrolife Technology Hub
- ES server with a valid licence file installed.

2 Vitrolife Technology Hub

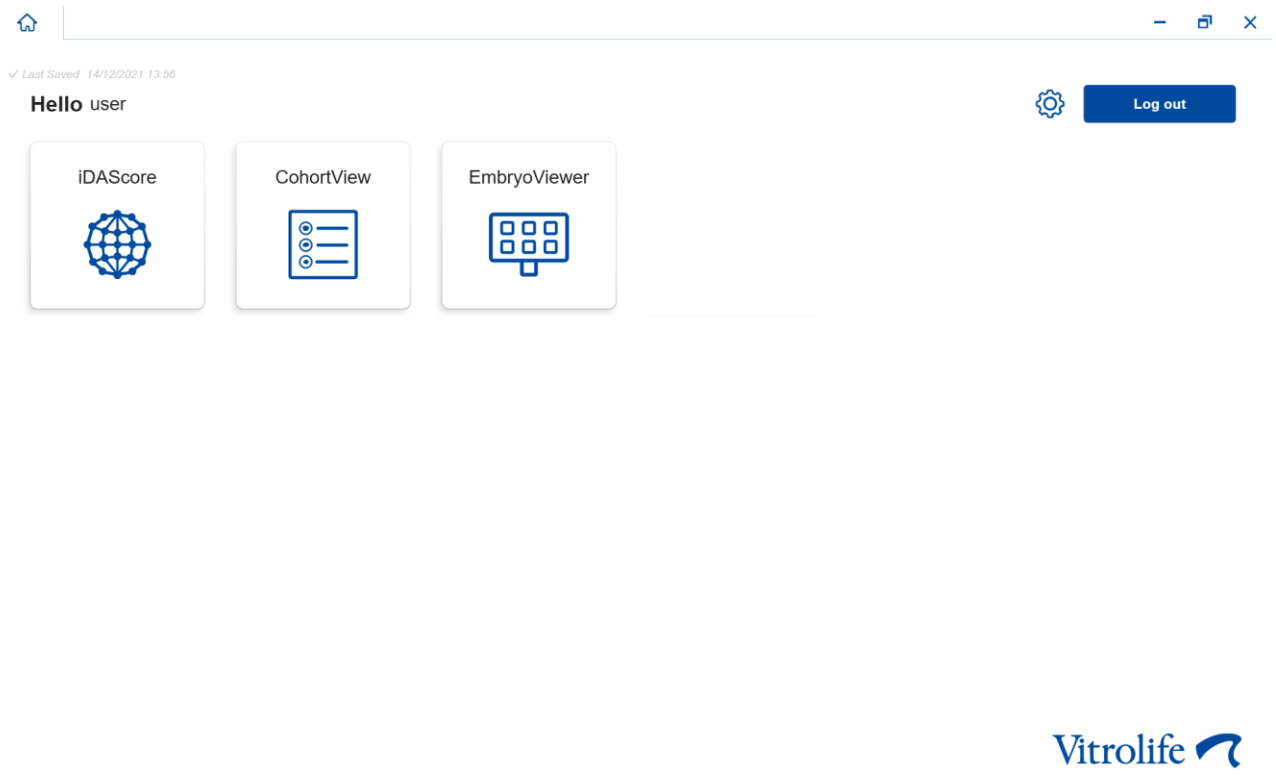
Vitrolife Technology Hub is the platform from which you access the modules used in your clinic. It is classified as class I in accordance with and conforms to the requirements of the Medical Device Regulation (EU) 2017/745.

2.1 Intended use

Vitrolife Technology Hub is a software platform used to execute software modules that are intended to support or be used as part of fertility treatment.

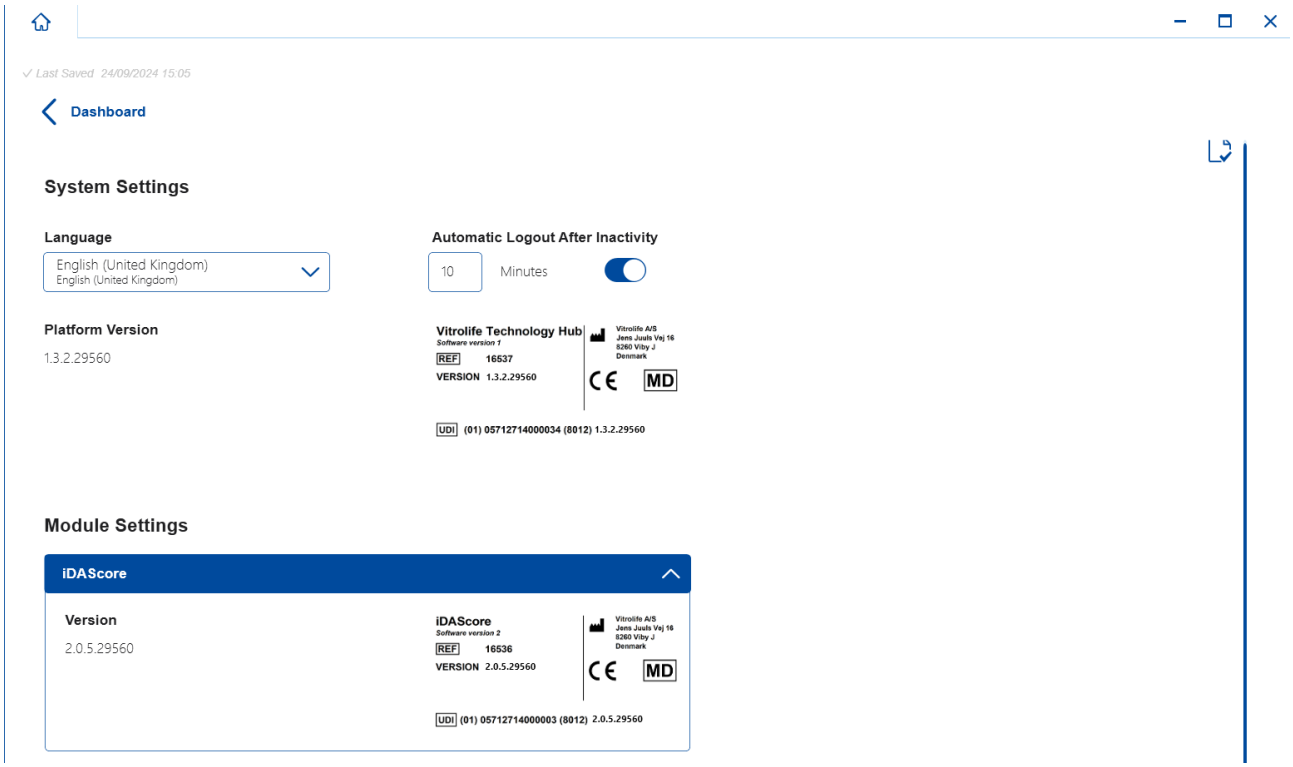
2.2 Using Vitrolife Technology Hub

To use a module in Vitrolife Technology Hub, double-click the Vitrolife Technology Hub desktop shortcut or start the program from the Windows start menu. Log in with your EmbryoViewer user name and password. You will now see the dashboard of Vitrolife Technology Hub with the modules used in your clinic.



Click a module to open it. If you open more than one module, each module will open on a new tab. You can close any open tab by clicking the X on the tab.

The settings icon next to the **Log out** button provides access to system and module settings.



Under **System Settings**, you can choose between available display languages in the **Language** drop-down list, set the idle period after which users are automatically logged out under **Automatic Logout After Inactivity** and see the current platform version under **Platform Version**. You can also see information about Vitrolife Technology Hub.

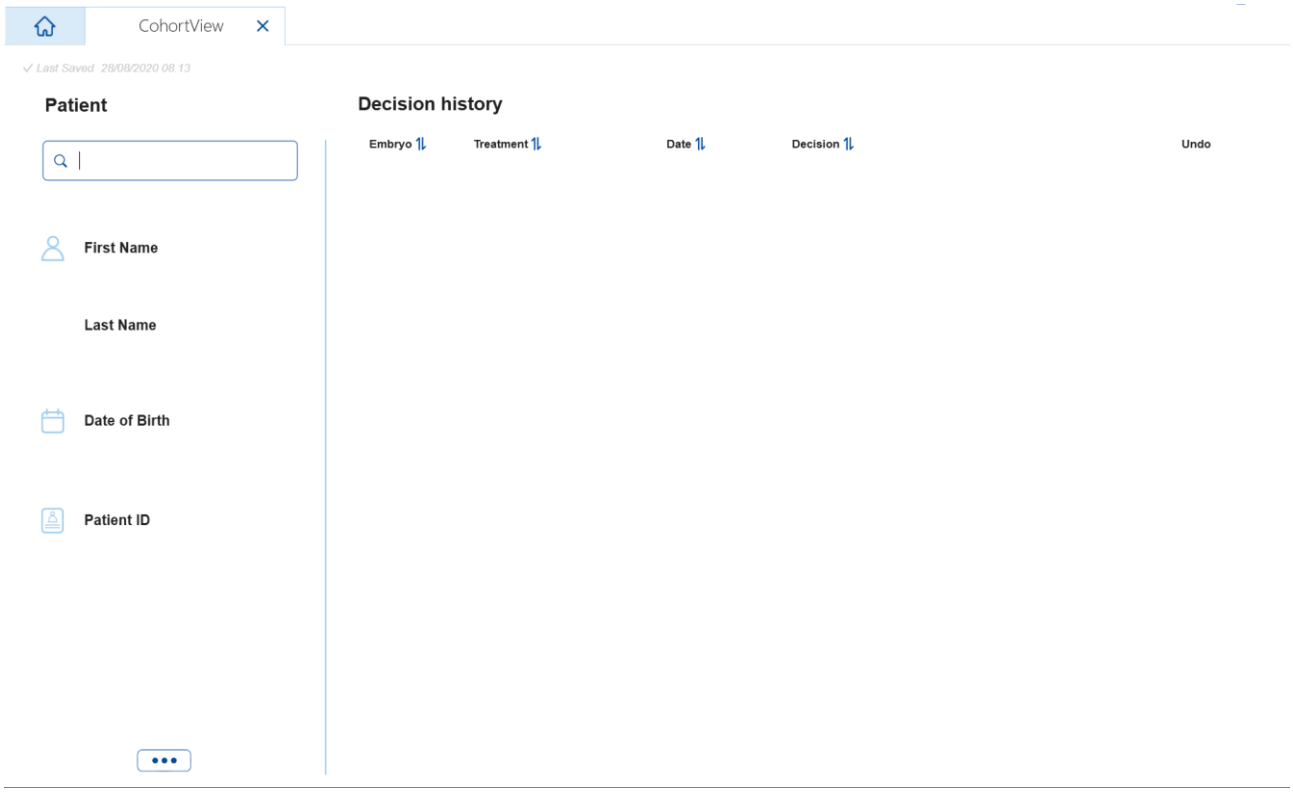
Under **Module Settings**, you can see the current version of a specific module. For some modules, you can also see other details such as the reference number and UDI (unique device identification) code. Click the arrow next to the module name to open or close this information.

Click the icon in the top right corner of the screen if you want to see the end user licence agreement. The agreement will be shown in the language you have selected in the **Language** drop-down list. Click the **Close** button or the X in the top right corner to close the agreement.

Click the **Dashboard** link to return to the dashboard.

3 CohortView – basic functionality

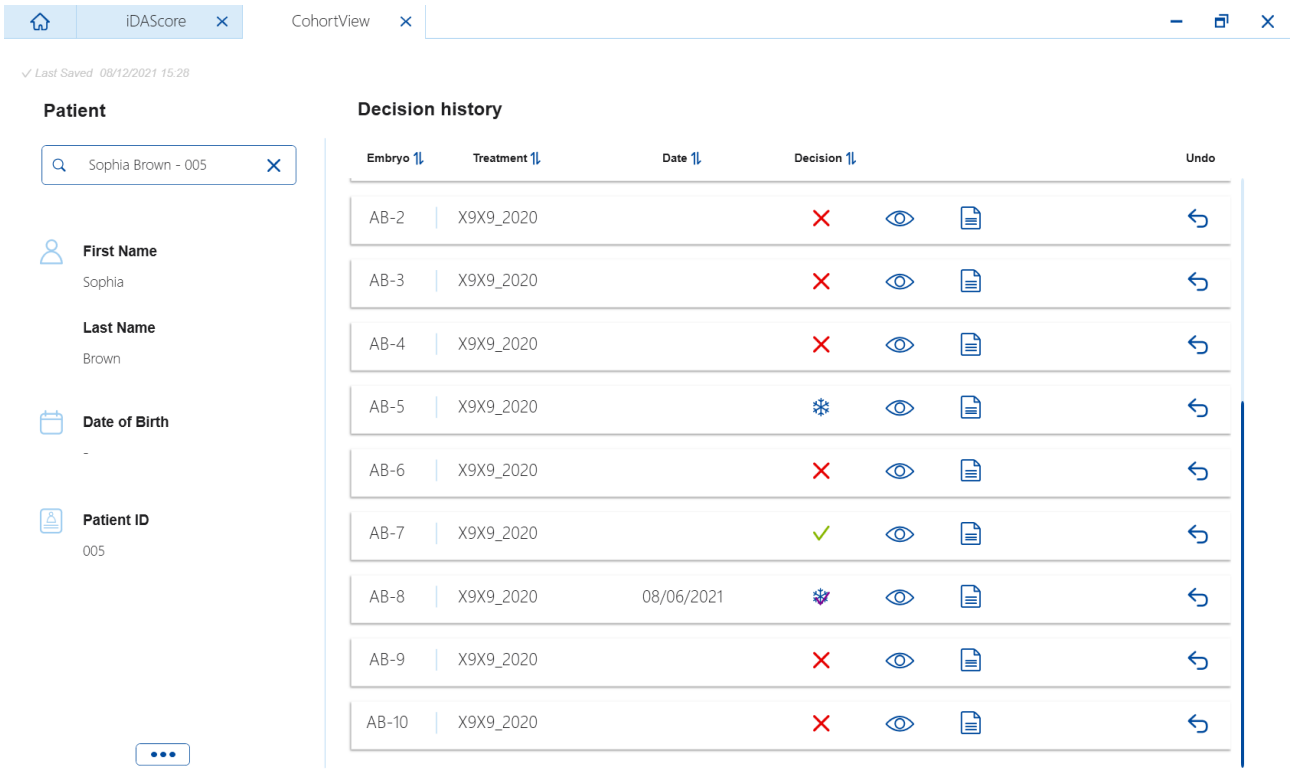
When you first open CohortView, the opening page contains no information.



Enter a patient name, a patient ID or a treatment ID in the search field in the left side of the screen to search for a specific patient or treatment.

The **First Name**, **Last Name**, **Date of Birth** and **Patient ID** fields are automatically populated with the patient's details.

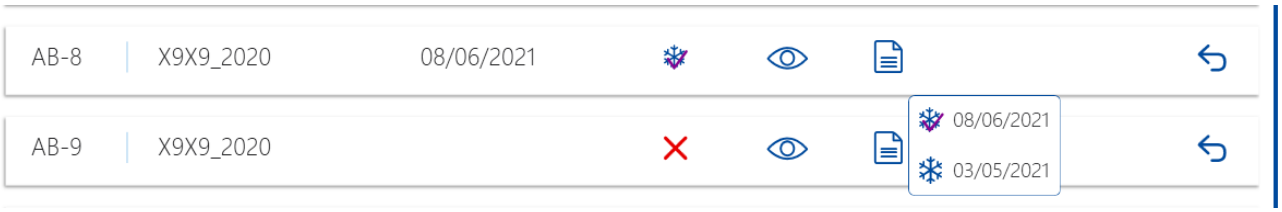
Under **Decision history** in the right side of the screen, a list of all the patient's embryos across all treatments is shown. The **Embryo** column contains the embryo's unique ID, and the **Treatment** column displays which treatment the embryo belongs to. The **Date** column contains the transfer date for transferred embryos, and the **Decision** column displays the decision made for each embryo in iDAScore or in the EmbryoViewer software.



You can sort the embryos by embryo ID, treatment, date or decision. Click the relevant heading once to sort the data in descending order or twice to sort the data in ascending order. By default, the embryos are displayed by embryo ID in ascending order. If you change the sorting, the view will revert to the default sorting next time you open the patient's data.

To see the last image taken of an embryo, place the cursor over the eye symbol without clicking the symbol. If you want to see the time-lapse video of the embryo, you can do so in the EmbryoViewer software.

If you have finalised your decisions in iDAScore, a report icon is displayed next to the eye symbol. Click the report icon to open the embryo decision report. If multiple decisions have been made for the embryo, multiple dates will be displayed when you place the cursor over the report icon without clicking it. The most recent report will be displayed at the top of the list. Click one of the dates to open the report in question.

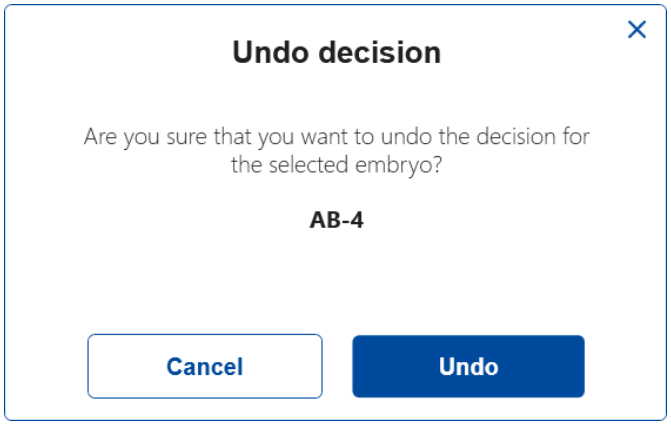


Click the button with the three dots in the lower left side of the screen to go directly to the EmbryoViewer software or another module in Vitrolife Technology Hub. Select an option on the list shown when you click the button. The currently selected patient's data will automatically open in the EmbryoViewer software or the selected module.

4 Making and resetting decisions

Decisions are made in iDAScore or in the EmbryoViewer software. You can reset a finalised decision in CohortView, but if you want to make a new decision, you must do so in iDAScore or in the EmbryoViewer software. See the iDAScore and EmbryoViewer user manuals for more information on how to make decisions.

To reset a decision in CohortView, click the arrow in the **Undo** column. Select **Undo** in the displayed dialogue box to confirm your choice and clear the **Decision** column, or select **Cancel** to close the dialogue box without resetting the decision.



Any changes are automatically saved and reflected in iDAScore and in the EmbryoViewer software.

If no decision has been made for an embryo, the **Decision** and **Undo** columns are empty.

5 Symbols and labels

Label	Description	Note
	Reference number	-
	Declaration by the manufacturer that the device meets all of the applicable requirements in the Medical Device Regulation (EU) 2017/745	Applicable to Vitrolife Technology Hub only.
	Medical device	Applicable to Vitrolife Technology Hub only.
	Unique device identifier	Applicable to Vitrolife Technology Hub only.
	Manufacturer name and address	See section 7.

6 Disposal of waste

In order to minimise 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.

7 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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