

iDAScore™

User manual

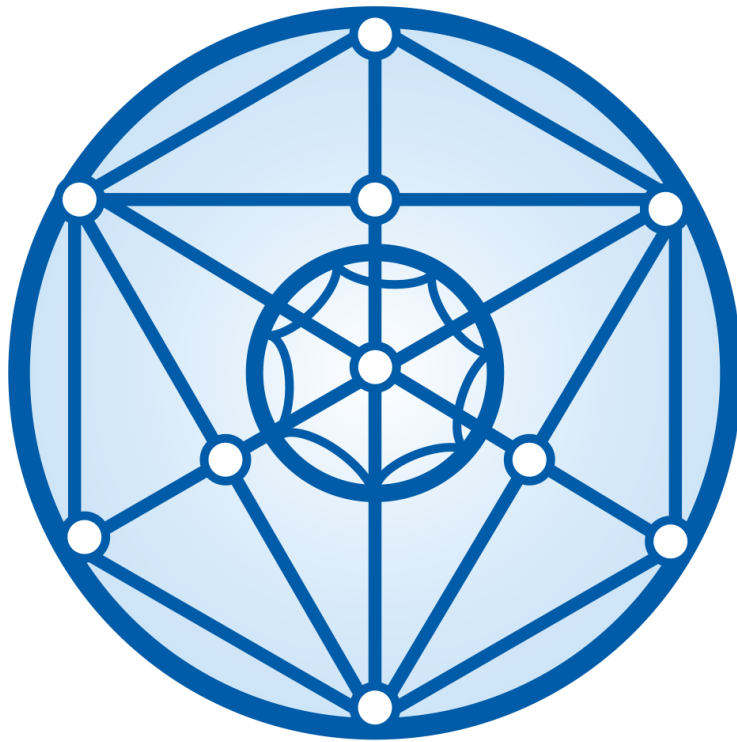


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1 Introduction

This user manual provides information on how to use iDAScore, which is designed to automatically identify embryos with the highest chance of implantation.

In the user manual, all references to “EmbryoScope” cover both EmbryoScope+, EmbryoScope Flex and EmbryoScope 8 time-lapse incubators. All references to “EmbryoSlide” cover both EmbryoSlide+, EmbryoSlide+ ic8 and EmbryoSlide Flex culture dishes.

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 iDAScore.

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 iDAScore.

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

1.2 Important restrictions and warnings

All users of iDAScore must agree to read and understand this user manual, observe the restrictions on 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 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
<ul style="list-style-type: none">• All rights in iDAScore belong to Vitrolife A/S. Your installation and use of iDAScore are subject to the terms of the end user licence agreement.• You may not copy, modify, decompile, reverse engineer, disassemble or convert iDAScore or assign, transfer, sell, rent or lease iDAScore to any third party.

WARNING

- iDAScore assigns a score to each embryo. The embryos with the lowest scores have the statistically poorest chance of implanting, and the embryos with the highest scores have the statistically best chance of implanting. The decision about which embryo(s) to transfer, freeze or avoid must always be made by the user after an assessment of the quality of all relevant embryos.

CAUTION

- iDAScore 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 iDAScore

iDAScore is designed to automatically identify embryos with the highest chance of implantation. It is an adjunct to clinical decision-making, and the final assessment and decision must be made by a medical professional.

iDAScore assigns a score to each embryo based on a deep learning neural network-based algorithm for predicting the viability of embryos cultured in an EmbryoScope time-lapse system.

The information used for scoring the embryos is received from the ES server. The ES server receives image data from the connected EmbryoScope(s).

CAUTION
<ul style="list-style-type: none">iDAScore assigns a score to each embryo. This score may be used to support, but never as a substitute for, the embryologist's decision.

iDAScore is classified as class I in accordance with and conforms to the requirements of the Medical Device Regulation (EU) 2017/745.

1.5 Intended use

The device evaluates early embryo development through acquired embryo time-lapse videos to assist embryo selection. The device assigns a score to each embryo that identifies embryos with the highest chance of implantation. The device is an adjunct to clinical decision-making, and the final assessment and decision must be made by a medical professional.

1.6 Indications for use

iDAScore is intended to be used for evaluation of embryos from IVF patients. iDAScore must be used together with an EmbryoScope time-lapse system.

1.7 Intended users

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

1.8 Clinical benefit

As an accessory to a medical device, iDAScore provides the indirect clinical benefit of improving the decision-making process by providing support for selection of embryos incubated in the incubator(s) connected to the system.

1.9 Proposed workarounds

There are currently no known anomalies in iDAScore.

1.10 Requirements for using iDAScore

To be able to use iDAScore, you need:

- An EmbryoScope
- EmbryoViewer software
- Vitrolife Technology Hub
- ES server with a valid licence file installed. The server hardware configuration must include a graphics card and an SSD hard disk.

Furthermore, the time-lapse video quality is important. You must ensure that:

- The embryo has been properly denuded and is free of e.g. cumulus cells
- The entire embryo is visible when the image acquisition is started
- The embryo is centred in the well and in focus during the entire period of culture
- No air bubbles are present in the well.

WARNING
<ul style="list-style-type: none">• iDAScore has not been sufficiently validated for use in treatments with interrupted embryo culture. Interrupted culture includes laser hatching on day 3 and 4 and continued culture after artificial blastocyst collapses for vitrification. These scores should be interpreted with caution. Standard handling such as medium changes does not constitute interrupted culture.

2 Vitrolife Technology Hub

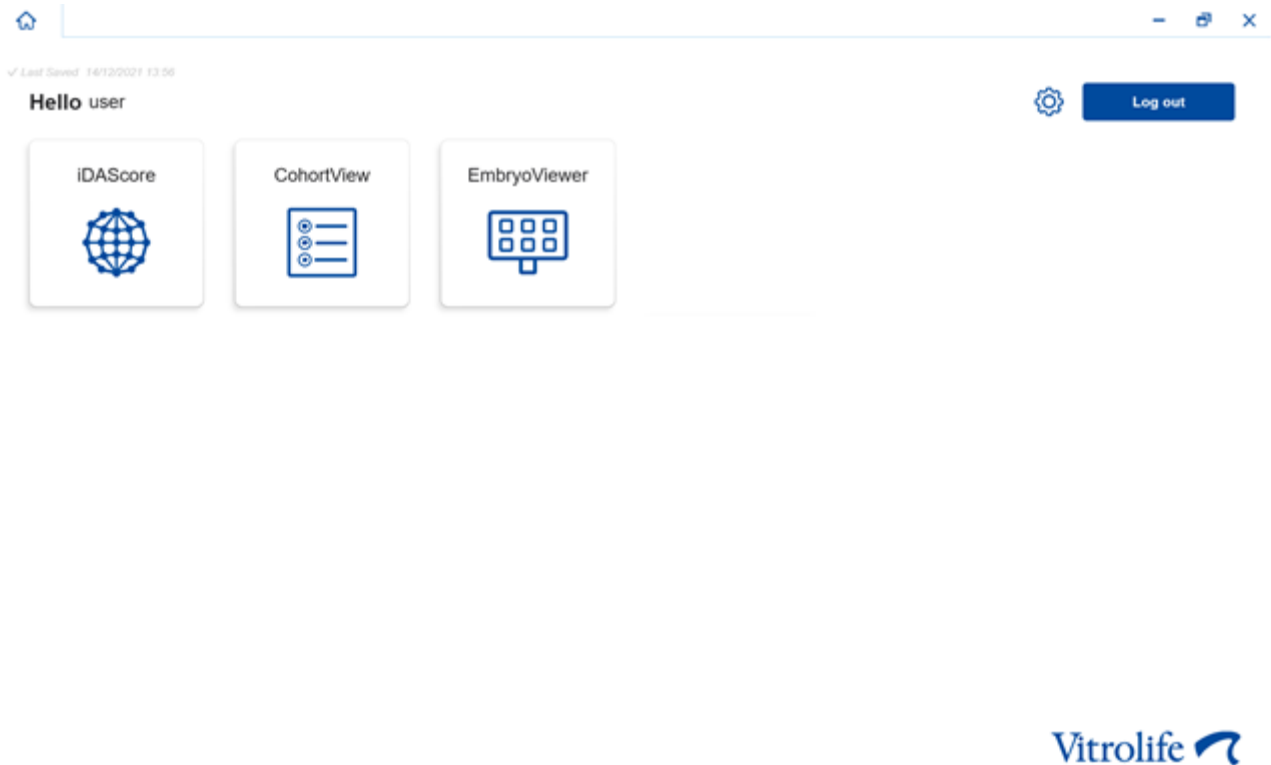
Vitrolife Technology Hub is the platform from which you access the modules used in your clinic. It is classified as class I in accordance with and conforms to the requirements of the Medical Device Regulation (EU) 2017/745.

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.

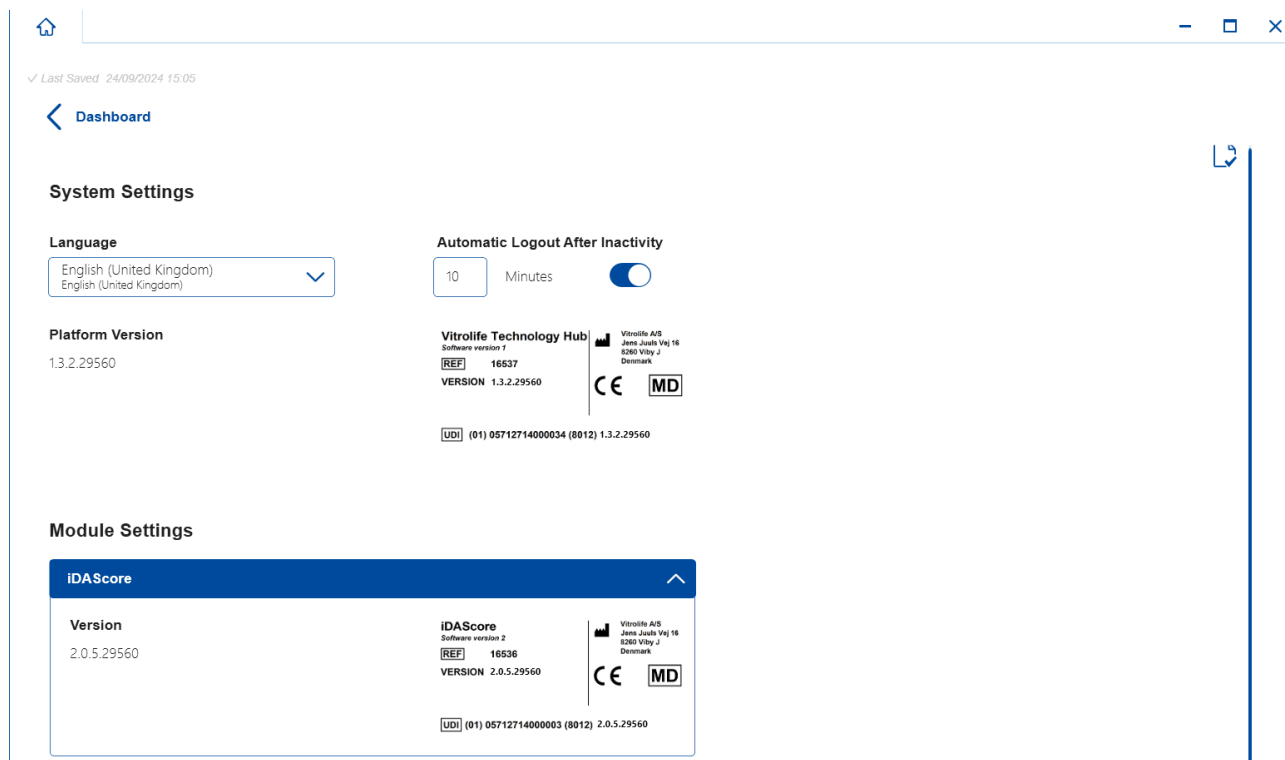
2.2 Using Vitrolife Technology Hub

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 iDAScore – basic functionality

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

The screenshot shows the iDAScore application interface. At the top, there is a browser tab labeled 'iDAScore' and a status bar indicating 'Last Saved: 03/12/2021 09:58'. The interface is divided into two main sections: 'Patient' on the left and 'Embryos' on the right. The 'Patient' section contains a search bar and four input fields: 'First Name', 'Last Name', 'Date of Birth', and 'Patient ID'. The 'Embryos' section displays a table with columns for 'Embryo', 'Score', 'Fresh', and 'All'. The 'Fresh' column has a radio button selected, and the 'All' column has a radio button selected. To the right of the 'Embryos' section, there is a 'Finalise' button and a 'Make a Decision' section with three buttons: a green checkmark, a blue snowflake, and a red X. Below these buttons are labels for 'Pronuclei' and 'Decision'.

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, and scores for the patient's embryos are calculated and displayed in the right side of the screen. Select **Fresh** to see scores for fresh embryos only or **All** to see scores for both fresh and frozen embryos. Fresh embryos are embryos that have been inseminated within the last 10 days.

If you want to see detailed patient and treatment information or apply a scoring model to the patient's embryos, you can do so in the EmbryoViewer software. See the EmbryoViewer user manual for more information on these functions.

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 Scores assigned to the embryos

All embryos are assigned a numerical score between 1.0 and 9.9, and the score bar appears dark grey until a decision is made for the embryo (see section 5). If no score can be calculated, the score bar appears light grey. Place the cursor over the dash in the **Score** column to see further details.



CAUTION

- The culture dish must be inserted into the incubator no later than 24 hours after the insemination for a score to be calculated.
- No score is displayed if it has been less than 39 hours after the insemination.

Scores are displayed on day 2, day 3, day 5 and day 6 of culture. For scores to be displayed on day 2, at least 39 hours must have elapsed after the insemination. Scores are then continuously calculated every time you open the patient's data until 84 hours after the insemination (day 3). After this time, no scores are calculated until at least 108 hours after the insemination (day 5).

No scores are displayed on day 1 and day 4, i.e. less than 39 hours after the insemination and between 85 and 107 hours after the insemination.

In summary, scores are displayed as follows during the period of culture:

- Day 1 (less than 39 hours after the insemination): no scores are displayed.
- Day 2 and 3 (39-84 hours after the insemination): scores are continuously calculated.
- Day 4 (85-107 hours after the insemination): no scores are displayed.
- Day 5 and 6 (108-148 hours after the insemination): scores are continuously calculated.

The embryos with the highest scores have the statistically best chance of implanting. The final decision about which embryos to transfer, freeze or avoid must always be made by the embryologist after careful consideration of each embryo. The scores may support that decision, but never function as a substitute.

If an embryo does not have two pronuclei (PN), no score is displayed for the embryo, and the PN value is displayed under **Pronuclei** with a warning symbol (!). You can change the PN value manually if required (see section 5.1).



If no PN estimate is available and the PN value has not been annotated or has been annotated as **NA**, a score is displayed for the embryo, and a warning symbol is displayed under **Pronuclei**. Place the cursor over the warning symbol to see further details.

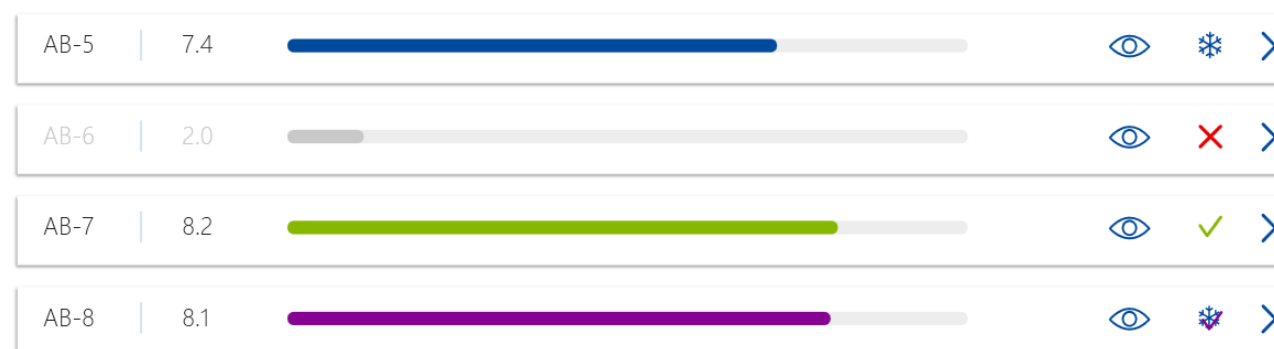


5 Selection of embryos

When embryo scores for a patient are displayed, you can use the decision buttons under **Make a Decision** to indicate which embryo(s) to transfer (green icon), freeze (blue icon) or avoid (red icon). The decision button with the green icon is used to select both fresh and frozen embryos for transfer. If you click one of the buttons, the corresponding icon will follow the cursor, and a check box appears under **Decision** for all embryos. Click the check box for all embryos to which you want to apply the decision. Click the same decision button again to return the cursor to its normal use, or click one of the other decision buttons to apply another decision to one or more embryos.

If you want to undo a decision, click the relevant decision button and then the check box for the embryo in question. This will clear the check box.

When you apply a decision to an embryo, the embryo's score bar changes colour accordingly. For embryos selected for fresh transfer, the score bar turns green. For embryos selected for freezing, it turns blue, and for frozen embryos selected for transfer, it turns purple. For embryos marked to be avoided, the entire row is dimmed.



5.1 Images, time-lapse videos and annotations

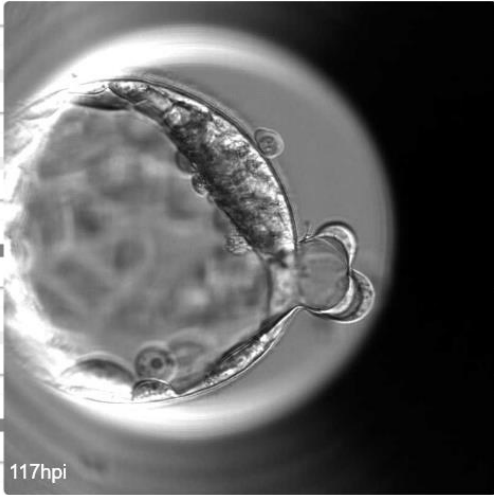
iDAScore lets you view embryo images and time-lapse videos to support your decisions. To see the last image taken of an embryo, place the cursor over the eye symbol without clicking the symbol.



Any added comments are displayed next to the image, and the time of image acquisition is displayed in the bottom left corner of the image. The time of image acquisition is the number of hours since the insemination (hpi).

Embryo Comment AB-7

AB-4	-			
AB-5	7.4			
AB-6	2.0			
AB-7	8.2			
AB-8	8.1			



117hpi

If you want to see further details of the embryo, click the arrow symbol. This opens a new page with additional information and options.

iDAScore

Patient Overview

First Name
Sophia

Last Name
Brown

Date of Birth
01/02/1990

Patient ID
005

AB-7

Treatment
X9X92020

Score
8.2

PN
2


Comment

Make a Decision

☒
☐
☐

EmbryoViewer: Annotation

AB-7



117.3hpi

Day 1
Day 2
Day 3
Day 4
Day 5

In the left side of the page, you can see the patient details and the score from the previous page. You can also see which treatment the embryo belongs to and the number of pronuclei (PN). A warning symbol (!) is displayed next to the **PN** field if no PN estimate is available and the number

- 13 -

of pronuclei has not been annotated. If you want to change the number of pronuclei, you can do so directly in the **PN** field. The change will automatically be reflected in the EmbryoViewer software. In the **Comment** field under this information, you can enter a comment if relevant. The decision buttons found on the previous page are also available here.

If you want to perform annotations or see any existing annotations in the EmbryoViewer software, click the **EmbryoViewer: Annotation** button to go directly to the **Annotate** page in the EmbryoViewer software. See the EmbryoViewer user manual for more information on annotations. Click the **Vitrolife Technology Hub** button in the EmbryoViewer software to return to iDAScore.

In the right side of the page, you can play a time-lapse video of the embryo. Use the playback buttons under the video to play or pause the video (middle button) or to move one image back (left button) or forward (right button). You can also drag the slider or click anywhere on the horizontal bar right under the video to go to a specific time point. If you prefer to use the keyboard, press the left or right arrow to move one image back or forward, respectively. This is useful if you want to check specific details. Press and hold the arrows to play the video backward or forward at high speed, or press the space bar to start or stop the video anytime.

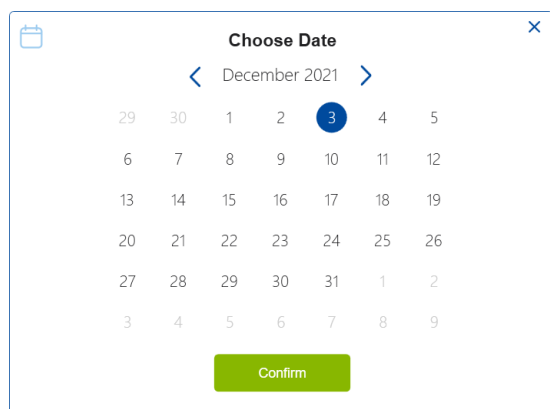
The two sliders next to the playback buttons can be used to adjust the brightness (upper slider) and contrast (lower slider) of the video.

To change the focal plane, drag the slider or click anywhere on the vertical bar to the right of the video. Alternatively, use the arrow up and down keyboard buttons.

When you have reviewed the embryo details, click the **Patient Overview** link to return to the overview page. Any changes or comments are automatically saved.


6 Finalisation and report generation

When you have made a decision for all relevant embryos, click the **Finalise** button. You will now be prompted to select a date. Select a date on the calendar shown, and click **Confirm**. The default date is the current date.




Choose Date							X
< December 2021 >							
29	30	1	2	3	4	5	
6	7	8	9	10	11	12	
13	14	15	16	17	18	19	
20	21	22	23	24	25	26	
27	28	29	30	31	1	2	
3	4	5	6	7	8	9	
Confirm							


An embryo decision report of all the embryos for which you made a decision is displayed. On the first page of this report, you can see how many embryos were selected for fresh transfer, for freezing, for frozen embryo transfer (FET) or avoided.


03/12/2021

Embryo Decision Report

 **First Name**
Sophia





Last Name
Brown

 **Date of Birth**
01/02/1990

 **Patient ID**
005


Summary

Decision Date 03/12/2021 **iDAScore version** 2.0.2

Decision	Number
 Transfer	1
 Freeze	4
 FET	0
 Avoid	10

Close

Save



The next page(s) contain details of the finalised embryos and the culture dish and instrument in which they were incubated. One page will be generated for each culture dish containing finalised embryos. The illustration shows which wells in the culture dish contained embryos selected to be transferred (green), embryos selected for freezing (blue) and embryos marked to be avoided (grey).



First Name
Sophia

Last Name
Brown



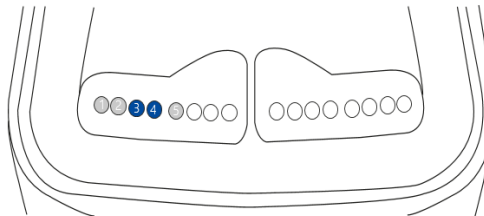
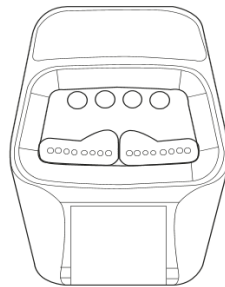
Date of Birth
01/02/1990



Patient ID
005

Culture Dish AA**Treatment** Y2Y22020**Dish ID** D2000.01.01_S10005_I0001_P**Instrument** ES+ 0001**Hours Past Insemination** 120.8

Embryo	iDAScore	Decision
AA-3	7.5	● Freeze
AA-4	8.7	● Freeze



First Name
Sophia

Last Name
Brown



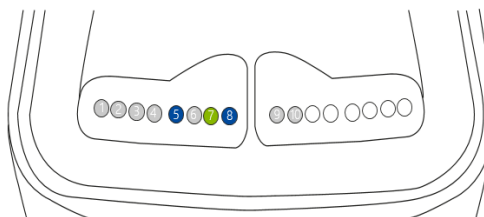
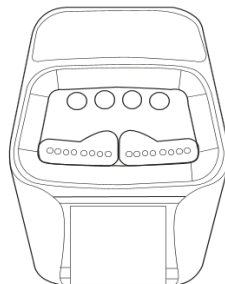
Date of Birth
01/02/1990



Patient ID
005

Culture Dish AB**Treatment** X9X92020**Dish ID** D2000.01.01_S10006_I0002_P**Instrument** ES+ 0002**Hours Past Insemination** 117.4

Embryo	iDAScore	Decision
AB-5	7.4	● Freeze
AB-7	8.2	● Transfer
AB-8	8.1	● Freeze



On the next page of the report, all embryos marked to be avoided are listed with treatment, culture dish ID and well number.



First Name
Sophia

Last Name
Brown



Date of Birth
01/02/1990



Patient ID
005

Avoid

Treatment	Dish ID	Well
Y2Y2_2020	D2000.01.01_S10005_I0001_P	1
Y2Y2_2020	D2000.01.01_S10005_I0001_P	2
Y2Y2_2020	D2000.01.01_S10005_I0001_P	5
X9X9_2020	D2000.01.01_S10006_I0002_P	1
X9X9_2020	D2000.01.01_S10006_I0002_P	2
X9X9_2020	D2000.01.01_S10006_I0002_P	3
X9X9_2020	D2000.01.01_S10006_I0002_P	4
X9X9_2020	D2000.01.01_S10006_I0002_P	6
X9X9_2020	D2000.01.01_S10006_I0002_P	9
X9X9_2020	D2000.01.01_S10006_I0002_P	10

The final page of the report contains a decision overview with scores and decisions for all embryos.



First Name
Sophia

Last Name
Brown



Date of Birth
01/02/1990



Patient ID
005

Decision overview

Treatment	Embryo	iDAScore	Hours Past Insemination	Decision
Y2Y2_2020	AA-1	1.7	120	● Avoid
Y2Y2_2020	AA-2	-	120	● Avoid
Y2Y2_2020	AA-3	7.5	120	● Freeze
Y2Y2_2020	AA-4	8.7	120	● Freeze
Y2Y2_2020	AA-5	1.9	120	● Avoid
X9X9_2020	AB-1	1.4	117	● Avoid
X9X9_2020	AB-2	1.5	117	● Avoid
X9X9_2020	AB-3	1.5	117	● Avoid
X9X9_2020	AB-4	-	117	● Avoid
X9X9_2020	AB-5	7.4	117	● Freeze
X9X9_2020	AB-6	2.0	117	● Avoid
X9X9_2020	AB-7	8.2	117	● Transfer
X9X9_2020	AB-8	8.1		

Close

Save



Click **Close** to close the report, or click **Save** to save the report in PDF format in a location of your choice. All reports automatically become available in CohortView, and you do not have to actively save them. Click the printer icon if you want to print the report.

After you finalise your decisions, all embryos selected for transfer or marked to be avoided will no longer be displayed. Only frozen embryos and embryos for which no decision has been made are now displayed, and the view automatically changes to **All**. If the patient has frozen embryos from previous treatments, they will also be displayed.

 iDAScore 

✓ Last Saved 03/12/2021 11:35

Patient

 Sophia Brown - 005 

 **First Name**
Sophia

Last Name
Brown

 **Date of Birth**
01/02/1990

Embryos

Finalise

Make a Decision
  

Embryo 

Score 

Fresh 

All 






Pronuclei 

Decision 

AA-3	7.5	<div><div></div></div>	  
AA-4	8.7	<div><div></div></div>	  
AB-5	7.4	<div><div></div></div>	  
AB-8	8.1	<div><div></div></div>	  

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7 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	-
	Medical device	-
	Unique device identifier	-
	Manufacturer name and address	See section 9.

8 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.

9 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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