

iDAScore™

User manual

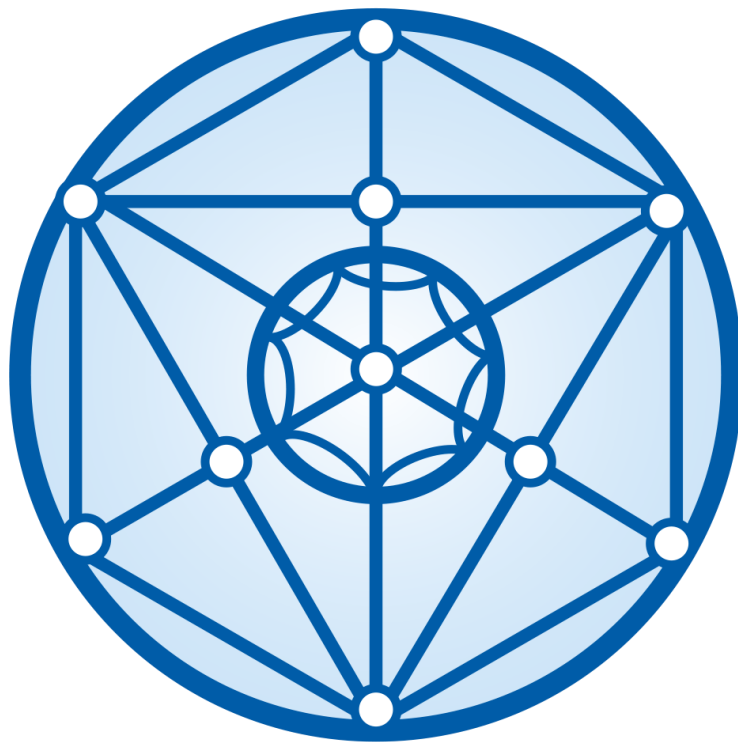


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1 Introduction

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.

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) and annotation data from the EmbryoViewer software.

CAUTION

- iDAScore assigns a score to each embryo in a selected EmbryoSlide culture dish. 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 and limitations in iDAScore.

1.10 Requirements for using iDAScore

To be able to use iDAScore, you need:

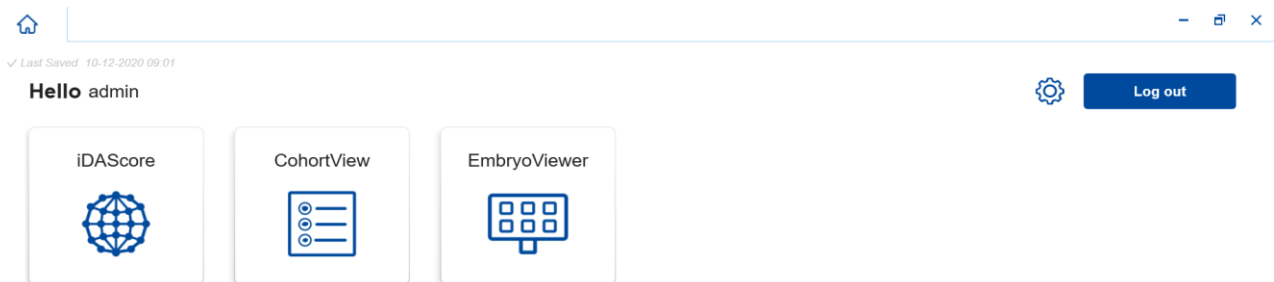
- An EmbryoScope
- EmbryoViewer software
- ES server with a valid licence file installed.

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 culture dish 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.

2 Vitrolife Technology Hub

To use a module in the Vitrolife Technology Hub, double-click the Vitrolife Technology Hub desktop shortcut or start the program from the Windows start menu. You will now see the home tab of the 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.

✓ Last Saved 10-12-2020 09:05

< **Dashboard**

System Settings

Language
English (United Kingdom) ▼

Automatic Logout After Inactivity
10 Minutes

Platform Version
1.2.0

Module Settings

iDAScore ▼

CohortView ▼

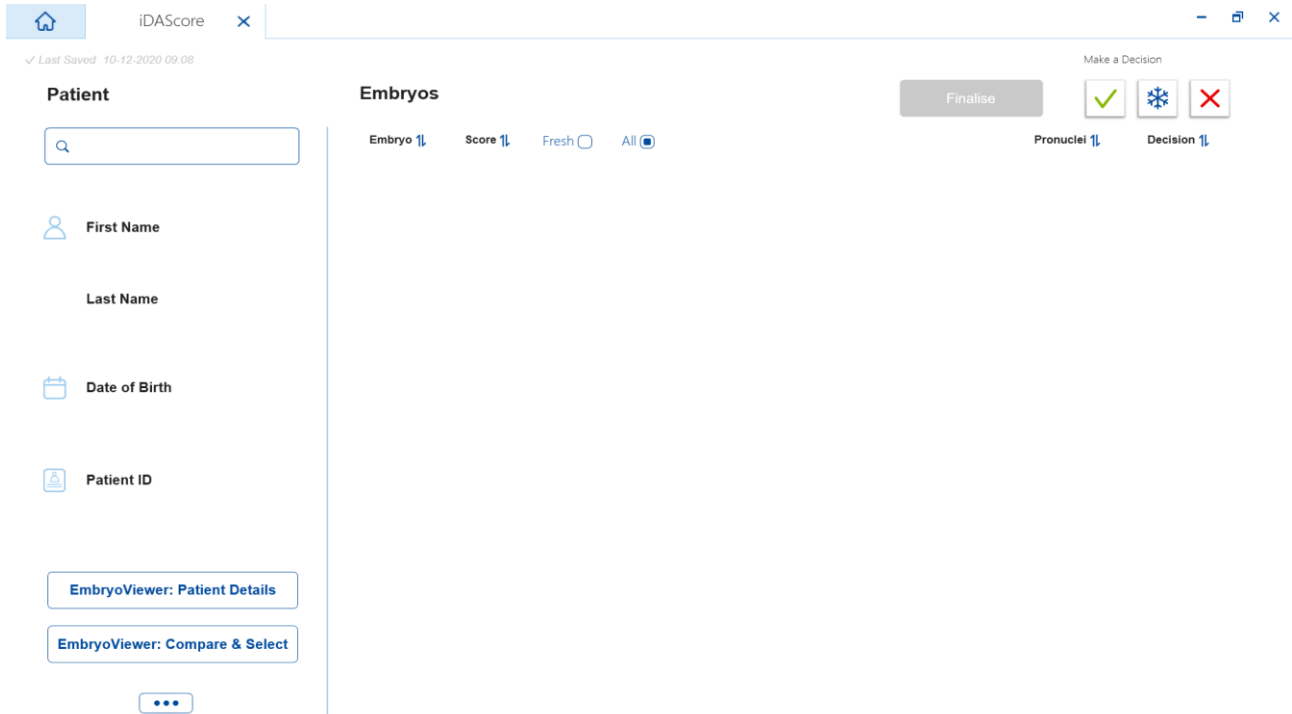
Under **System Settings**, you can choose between available display languages in the **Language** drop-down list, set the idle period after which users are automatically logged out under **Automatic Logout After Inactivity** and see the current platform version under **Platform Version**.

Under **Module Settings**, you can see the current version and the UDI (unique device identification) code of a specific module. Click the arrow next to the module name to open or close this information.

Click the **Dashboard** link to return to the module overview.

3 iDAScore – basic functionality

When you first open iDAScore, 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, 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.

The screenshot displays the iDAScore software interface. On the left, the 'Patient' section shows details for Sophia Brown, born 01-02-1990, with Patient ID 005. Below this are buttons for 'EmbryoViewer: Patient Details' and 'EmbryoViewer: Compare & Select'. The main area is titled 'Embryos' and features a table with columns for Embryo ID, Score, Fresh/All status, Pronuclei, and Decision. A 'Finalise' button and 'Make a Decision' icons (checkmark, snowflake, X) are at the top right. The table lists embryos AB-1 through AB-9 with their respective scores and progress bars.

Embryo	Score	Fresh	All	Pronuclei	Decision
AB-1	3.7	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
AB-2	2.1	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
AB-3	2.0	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
AB-4	-	<input type="checkbox"/>	<input checked="" type="checkbox"/>	1 PN!	
AB-5	9.1	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
AB-6	4.5	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
AB-7	7.2	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
AB-8	8.9	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
AB-9	4.0	<input type="checkbox"/>	<input checked="" type="checkbox"/>		

You can sort the calculations by embryo ID, score or number of pronuclei. If a decision has been made for the embryos (see section 5), you can also sort by 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 calculations 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.

If you want to see detailed patient and treatment information or apply a scoring model to the patient's embryos, you can use the two buttons in the lower left side of the screen to go directly to either the **Patient Details** or the **Compare & Select** page in the EmbryoViewer software. See the EmbryoViewer user manual for more information on these pages.

[EmbryoViewer: Patient Details](#)

[EmbryoViewer: Compare & Select](#)

Click the button with the three dots in the lower left side of the screen to go directly to another module in the Vitrolife Technology Hub. Select an option on the list shown when you click the button.



4 Scores assigned to the embryos

All embryos are assigned a numerical score between 1 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 information is shown if the culture dish has been running for less than 112 hours.

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.

The screenshot shows the 'Embryos' section of the iDAScore interface. At the top right, there is a 'Make a Decision' section with three buttons: a green checkmark, a blue snowflake, and a red 'X'. Below this is a green 'Finalise' button. The main table has columns for 'Embryo', 'Score', 'Fresh' (radio button), 'All' (radio button), 'Pronuclei', and 'Decision'. The table contains four rows of embryo data:

Embryo	Score	Fresh	All	Pronuclei	Decision
AB-5	9.1	<input type="checkbox"/>	<input checked="" type="checkbox"/>		Green checkmark
AB-7	7.2	<input type="checkbox"/>	<input type="checkbox"/>		Blue snowflake
AB-8	8.9	<input type="checkbox"/>	<input type="checkbox"/>		Purple snowflake
AB-9	4.0	<input type="checkbox"/>	<input type="checkbox"/>		Red X

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.

This is a close-up of the first row in the table from the previous screenshot. The embryo ID is 'AB-5' and the score is '9.1'. The score bar is green. The 'Decision' column shows a blue eye icon, which is highlighted with a red square. A right-pointing arrow is also visible in the 'Decision' column.

Any added comments are displayed next to the image.

The screenshot shows a list of embryos on the left and a central image of embryo AB-5. The list includes:

Embryo ID	Score	Progress Bar
AB-2	2.1	Short bar
AB-3	2.0	Short bar
AB-4	-	Empty bar
AB-5	9.1	Long bar
AB-6	4.5	Medium bar

The central image shows a microscopic view of embryo AB-5. To the right of the image is a 'Decision' panel with five rows, each containing an eye icon and a right-pointing arrow.

If you want to see further details of the embryo, click the arrow symbol.

This is a close-up of the AB-5 entry from the list. It shows the text 'AB-5 | 9.1' followed by a progress bar, an eye icon, and a right-pointing arrow icon. The arrow icon is highlighted with a red square.

This opens a new page with additional information and options.

The screenshot shows the 'Patient Overview' page for embryo AB-5. The page includes:

- Patient Overview:** First Name: Sophia, Last Name: Brown, Date of Birth: 01-02-1990, Patient ID: 005.
- AB-5 Treatment:** X9X92020
- Score:** 9.1
- PN:** 2
- Comment:** A text input field.
- Make a Decision:** Three buttons: a green checkmark (selected), a blue snowflake, and a red X.
- EmbryoViewer: Annotation:** A button at the bottom left.
- Image:** A large image of embryo AB-5 with a vertical color scale on the right (ranging from -75 to 75) and a horizontal timeline at the bottom (Day 1 to 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 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 **IDA** 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.

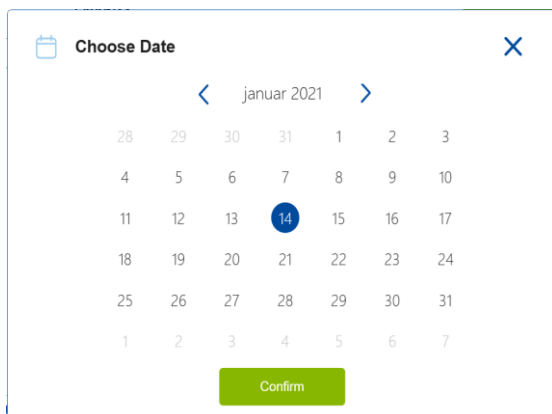
The two sliders next to the playback buttons can be used to adjust the brightness (upper slider) and contrast (lower slider) of the video.

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**.



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.

14-01-2021


Embryo Decision Report

First Name Sophia **Last Name** Brown **Date of Birth** 01-02-1990 **Patient ID** 005

Summary

Decision Date 14-01-2021

Decision	Number
<input checked="" type="radio"/> Transfer	1
<input checked="" type="radio"/> Freeze	5
<input type="radio"/> FET	0
<input type="radio"/> Avoid	9

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).



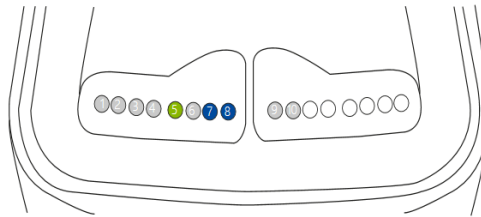
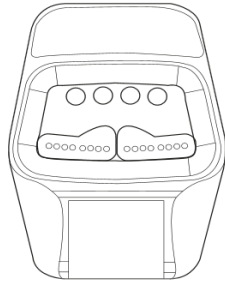
14-01-2021

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	Score	Decision
AB-5	9.1	● Transfer
AB-7	7.2	● Freeze
AB-8	8.9	● Freeze



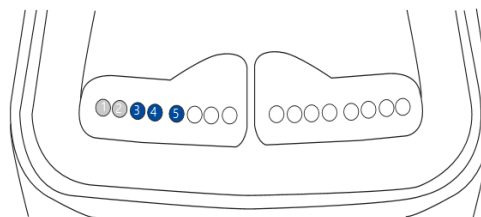
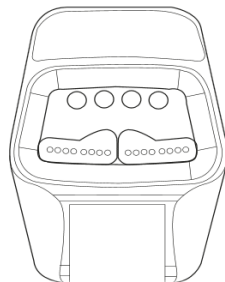
14-01-2021

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	Score	Decision
AA-3	9.2	● Freeze
AA-4	9.4	● Freeze
AA-5	5.8	● Freeze





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

14-01-2021

 **First Name**
Sophia


Last Name
Brown

 **Date of Birth**
01-02-1990

 **Patient ID**
005

Avoid

Treatment	Dish ID	Well
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
Y2V2_2020	D2000.01.01_S10005_I0001_P	1
Y2V2_2020	D2000.01.01_S10005_I0001_P	2

Close Save 





Click **Close** to close the report without saving it, or click **Save** to save the report in PDF format in a location of your choice. 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.

The screenshot shows the iDAScore web application interface. On the left, the 'Patient' section displays details for Sophia Brown - 005, including her first name, last name, date of birth (01-02-1990), and patient ID (005). The main area is titled 'Embryos' and shows a list of five embryos with their scores and decision options. The embryos are AB-7 (7.2), AB-8 (8.9), AA-3 (9.2), AA-4 (9.4), and AA-5 (5.8). Each embryo has a progress bar and icons for 'Pronuclei' and 'Decision'. A 'Finalise' button is visible at the top right of the embryo list.

Embryo	Score	Fresh	All	Pronuclei	Decision
AB-7	7.2	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
AB-8	8.9	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
AA-3	9.2	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
AA-4	9.4	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
AA-5	5.8	<input type="checkbox"/>	<input checked="" type="checkbox"/>		

7 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 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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