

KIDScore™ decision support tool

User manual



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1 Introduction

This user manual provides information on how to use the KIDScore decision support tool. The tool is used in conjunction with one or more models. Information related to the model used in your specific clinic is included in the relevant appendix.

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 the KIDScore decision support tool.

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 KIDScore decision support tool.

1.2 Important restrictions and warnings

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

RESTRICTIONS ON USE

- All rights in the KIDScore models belong to Vitrolife A/S. Your installation and use of a model are subject to the terms of the end-user license agreement.
- You may not copy, modify, decompile, reverse engineer, disassemble or convert a KIDScore model or assign, transfer, sell, rent or lease a model to any third party.

WARNING

- KIDScore models may only be used by clinic personnel who have been properly trained in their function and applicability by Vitrolife A/S. Users must be qualified to operate the tool and qualified to perform procedures associated with tool use in accordance with local qualification standards.

WARNING

- The KIDScore model 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. However, there may be parameters not included in the model that are also indicative of implantation potential. The decision about which embryo(s) to transfer must therefore always be made by the user after an assessment of the quality of all relevant embryos.

WARNING

- KIDScore models 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.

1.3 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.

1.4 Purpose of the KIDScore decision support tool

The KIDScore decision support tool is designed to support embryologists in their decision about which embryos to transfer, freeze or avoid. The tool is an add-on to the EmbryoViewer software. It is used in the **Compare & Select** function.

CAUTION

- The model 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.

The KIDScore decision support tool is a class I medical device that conforms to the requirements of the Medical Device Regulation (EU) 2017/745.

1.5 Intended use

The KIDScore tool is a decision support tool intended to be used together with a time-lapse incubator as part of fertility treatment.

1.6 Indications for use

The KIDScore decision support tool is used in conjunction with one or more models, e.g. the KIDScore D3 and KIDScore D5 models defined by Vitrolife. KIDScore D5 is not available in the US.

1.6.1 The KIDScore D3 model

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 and EmbryoScope+ time-lapse incubator systems.

1.6.2 The KIDScore D5 model

Not applicable as KIDScore D5 is not available in the US.

1.7 Intended users

Embryologists, other laboratory personnel and clinic staff at IVF clinics trained by Vitrolife A/S-certified instructors.

1.8 Clinical benefit

As an accessory to a medical device, the KIDScore decision support tool 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.

2 Requirements for using the KIDScore decision support tool

This section details the requirements that must be met in order to use the KIDScore decision support tool.

2.1 Technical requirements

The KIDScore decision support tool consists of one or more models working in conjunction with the EmbryoViewer software. To be able to use the tool, you need to have access to the following:

- For the KIDScore D3 model:
 - EmbryoViewer software with the **Compare & Select** function included, version 5.1 or later.
 - ES server version 5.1 or later.
- For the KIDScore D5 model (not available in the US):
 - EmbryoViewer software with the **Compare & Select** function included, version 5.4 or later.
 - ES server version 5.4 or later.

2.2 Annotation requirements

WARNING
<ul style="list-style-type: none">• If the annotations performed in the clinic are not consistent, the data will be less reliable and therefore less valuable, and the scores may be misleading rather than supporting.

In addition to following a consistent annotation method in your clinic, clinic personnel also need to annotate a number of mandatory variables that are used by the model for assigning a score to each embryo on the **Compare & Select** page of the EmbryoViewer software. The variables that have to be annotated in your clinic are specified in the relevant appendix to this user manual.

3 The scores assigned by the KIDScore decision support tool

The model underlying the tool is based on a number of parameters that are related to either embryo morphology or development stage. These are the parameters that the model takes into account when assigning a score to the embryos.

The score is based on your annotations, and it indicates how well the development pattern of a specific embryo satisfies the requirements of the model.

The embryos may be assigned a range of different scores. According to the model criteria, the lowest score is the least favorable, and the highest score is the most favorable.

See the relevant appendix for a further description of the scores assigned by the specific model applied in your clinic.

4 Importing a model for the KIDScore decision support tool

Follow this procedure to start using the KIDScore decision support tool:

1. Place the model made available by Vitrolife A/S in a folder that you can access from the computer that runs the EmbryoViewer software.
2. From the **Models** tab of the **Settings** page in the EmbryoViewer software, click the **Import** button. Then select the forwarded file from the folder where it was saved, and click **Open**.

Active	Name	Type	Creator	Date
<input checked="" type="checkbox"/>	Model name	Additive	ADMIN	2014-10-28

Figure 1: Import button on the Settings page, the Models tab.

3. Read and accept the terms of use.
4. Click **OK** in the displayed message.

When you first import a model, it is imported with a fixed name and version number. Once the model has been imported, you cannot change these data. However, in case you are importing a model with a name that already exists, you will be asked to specify a different name during the import.

After the import, the new model appears in the list on the **Models** tab of the **Settings** page. The page will specify that this model is provided by Vitrolife A/S:

The screenshot displays the 'Models' tab in the KIDScore decision support tool. The interface is divided into several sections:

- Models List:** A table showing imported models. The selected model is 'KIDScoreD3 v1.3' by Vitrolife, imported on 2022-03-16.
- Selected model:** A table listing variables and their min/max values for the selected model.

Variable	Min	Max
Information - NOT2PN	-	-
Information - IPNF	-	-
Information - t2	-	-
Information - t3	-	-
Information - t4	-	-
Information - t5	-	-
Information - t8	-	-
Information - cells66	-	-
- Model Details:** A detailed view of the 'KIDScoreD3 v1.3' model.
 - Model Name:** KIDScoreD3 v1.3
 - Model Type:** Imported
 - Creator:** Vitrolife
 - Model Description:** KIDScore D3 is defined by Vitrolife A/S based on the knowledge and experience extracted from our available KID data (please see the use manual for the EmbryoViewer software for a definition of KID data). The model focuses on which embryos to avoid rather than which embryos to select. It is thus a model which is based on avoidance criteria rather than selection criteria. The model will apply the avoidance criteria to the embryos and...
 - Custom Expressions:** A table with columns for Name and Expression. One expression is listed: 'cells66' with the expression 'cells(56)'.
 - Model Definition:** A table with columns for Variable, Description, Min, Max, and Classification.

Variable	Description	Min	Max	Classification
NOT2PN	Info			
IPNF	Info			
t2	Info			
t3	Info			
t4	Info			
t5	Info			
t8	Info			
cells66	Info			
 - Model Provided By:** Vitrolife A/S. Includes the Vitrolife logo and a license agreement section.
 - License Agreement:** Vitrolife A/S End-User License Agreement for KIDScore D3 Model. The agreement states that the installation and use of this KIDScore D3 model is subject to the terms and conditions stated below. It includes a disclaimer of warranties and a statement that the model is provided as a non-exclusive, non-transferable, and non-sub-licensable license.
 - Product Information:** KIDScore D3 Software version 1.3.0.27527, Vitrolife A/S, James Smith Way 10, 8200 Væby J, Denmark. Includes CE and MD marks and a UDI (01) 0512714675317 (0012) 1.3.0.27527.

Figure 2: Example of a D3 model provided by Vitrolife A/S.

4.1 Troubleshooting the import

If a model import error message is displayed, a problem has occurred while importing the model. This may be due to one of the following reasons:

- There may be a problem with the license file on your ES server. Contact Vitrolife for help.
- The model you are trying to import is not defined by Vitrolife A/S.
- The model has indeed been defined by Vitrolife A/S, but it was not made available directly to you by Vitrolife A/S. Contact us for help.

5 General workflow overview

This section provides a general overview of the process to follow when you want to use the KIDScore decision support tool:

1. Import a model for the KIDScore decision support tool (follow the procedure in section 4).
2. On the **Annotate** page of the EmbryoViewer software, annotate at least the mandatory variables for the embryos in a selected EmbryoSlide culture dish.

See the user manual for the EmbryoViewer software for a description of the **Annotate** page.

See the appendix that describes the model applied in your specific clinic.

Heidi Schmitt, X1X1_2020, well: AA-1 Embryo ID: AA1

Anno. Tool	Value	Well	Dec.	Progress
PN	2	AA-1		100 %
t2	28.5 h	AA-2		0 %
t3	30.9 h	AA-3		0 %
t4	31.2 h	AA-4		0 %
t5	42.8 h	AA-5		0 %
tB	77.6 h	AA-6		0 %
ICM	A	AA-7		0 %
TE	B	AA-8		0 %
		AA-9		0 %
		AA-10		0 %
		AA-11		0 %
		AA-12		0 %
		AA-13		0 %
		AA-14		0 %
		AA-15		0 %
		AA-16		0 %

Comments

111.9h

Strategy: KIDScore D5 v3 Annotation

Step by: Variable Well

3. On the **View Running** or the **View All Slides** page, select the annotated EmbryoSlide culture dish. Then click on **Compare & Select** in the navigation panel.
4. From the drop-down list on the **Compare & Select** page, select the desired model and apply it to the embryos in the current EmbryoSlide culture dish.

The model now assigns a numerical score to each embryo. The embryos with the highest scores have the statistically best chance of implanting. Note, however, that parameters not included in the model may also affect the embryo quality.

Well	Dec.	Current score	NOT2PN	t2	t3	t4	t5	tB	ICM	TE	Last stage	Morph. grade	Last image	Saved score
AB-1		6.1	●	25.5	38.3	39.6	50.5	109.7	B	B		B		
AB-2		6.6	●	25.8	38.3	40.2	53.6	103.7	B	B		EB		
AB-3		8.4	●	27.7	40.5	41.3	53.9	103.9	B	A		EB		
AB-4		6.2	●	25.8	39.1	39.2	55.5	106.6	B	B		EB		

Current Model
 KIDScoreD5 v3
 Created 2018-11-01 by Vitrolife

Saved Model
 No saved model

Transfer Info
 Transfer Date: 2019-07-02

View All Patient Embryos

5. Click **Save**.
6. You may apply an additional model to the embryos to also take other parameters not included in the KIDScore model into account. To do this:
 - a. Select a user-defined model and score the embryos by using that model.
 - b. Verify and compare the results. The scores assigned by the KIDScore model in the previous steps appear in the **Saved score** column.

Examples of user-defined parameters

Well	Dec.	Current score	UNEVEN2	UNEVEN4	MN2	MN4	Frag-2	Coll. Count	Last stage	Morph. grade	Last image	Saved score
AB-1		NA	●	●	●	●	5.0	0.0		B		6.1
AB-2		NA	●	●	●	●	5.0	1.0		EB		6.6
AB-3		NA	●	●	●	●	20.0	0.0		EB		8.4
AB-4		NA	●	●	●	●	10.0	2.0		EB		6.2

Current Model
 Info example
 Created 2019-06-04 by ADMIN

Saved Model
 KIDScoreD5 v3
 Saved 2019-07-02 15:57:22 by ADMIN

Transfer Info
 Transfer Date: 2019-07-02

View All Patient Embryos

7. Carefully examine the scored embryos and select them for either fresh transfer , frozen transfer , freezing , avoidance or later decision .





When a score has been assigned to each embryo by the KIDScore model, the embryos with the highest score are those with the statistically best chance of implanting. However, this does not necessarily imply that these are the embryos best suited for transfer.

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

WARNING
<ul style="list-style-type: none"> The KIDScore model 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. However, there may be parameters not included in the model that are also indicative of implantation potential. The decision about which embryo(s) to transfer must therefore always be made by the user after an assessment of the quality of all relevant embryos.

CAUTION
<ul style="list-style-type: none"> In rare cases, the model may assign the highest score to an embryo with a very poor morphology although morphologically superior embryos are available. In this case, consider why the model gave that result and whether an annotation was incorrect.

6 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 8.

7 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.

8 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 two working days)



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