fertoolity

OSIS Ovary

Instructions for Use

OSIS (Online System for Image Segmentations)
Instructions for Use version: 1.0
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1. INTRODUCTION

1.1.   Intended use

Online Ultrasound Image Segmentation System (OSIS) Ovary is an online platform based on web technology, which uses Artificial Intelligence (Deep Learning), with the purpose of providing objective anatomical measurements of the different ovarian follicles (folliculometry) from three-dimensional transvaginal ultrasound (3D). The software runs on a centralized server and its results can be accessed via the browser of a standard "off-the-shelf" computer. OSIS Ovary can be used to perform automatic segmentation, 3D rendering of the segmentation, quantification of ovarian follicles, and providing quantitative measurements of ovarian follicles. This device is indicated for

monitoring the treatment of adult women, mainly women undergoing cycles of controlled ovarian stimulation (COS). It is not indicated for pediatric use.

1.2. Intended user

OSIS Ovary is intended for use by healthcare professionals, to be used only by qualified personnel assigned to the patient.

1.3. About these instructions for use

- Read and understand these instructions for use before attempting to use OSIS Ovary.
- Instructions for use are available in the Help option of the OSIS Ovary platform, as well as in the OSIS Ovary label itself, under About. The instructions for use of OSIS Ovary can only be accessed by users of the platform, using their email and password.
- Instructions for use are available in PDF only. To consult them you can use the free reader available at: https://get.adobe.com/uk/reader/.
- These instructions for use are provided in electronic format only. If you need them in printed format, please contact Fertoolity team at info@fertoolity.com and ask for paper instructions. To do this, you must provide a Name and Surname associated with an OSIS Ovary user, a telephone number, an email, and a physical address where you wish to receive the instructions for use on paper. The user will receive the instructions for use on paper, at no additional cost, within 7 working days after the request is received.
- It is recommended that the user retain these instructions for use with the product for future reference.
- The availability of some functions or features depends on the probe and ultrasound system used. Refer to the instructions for use of your ultrasound device for further reference.

- The images in these instructions for use are for ease of understanding by the user only. In some cases, they may differ slightly from what you see on the screen.
- All references to the regulations/standards and their revisions are valid at the time of publication of these instructions for use.

1.4. Declaration of conformity

This product conforms to the following standards and regulations:

- MDR 2017/745: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
- EN 62304: Software for medical devices - Software lifecycle processes.
- EN 62366: Medical devices - Application of usability engineering to medical devices

- ISO 14971 Medical devices - Application of risk management to medical devices

1.5. Security Notes

- OSIS Ovary platform is a diagnostic assistance tool. In no way does it present, predict, suggest, or prognoses the patient's diagnosis.
- The final diagnosis of the study is the absolute responsibility of the professional, so he/she must verify the results provided by the platform before finalizing the analysis of the cases. A case should not be closed or concluded automatically without first checking that the results provided by the platform are correct.
- Do not include personal information of the patient during the export of data from the ultrasound that may compromise their identity.
- Before exporting images to OSIS Ovary from your ultrasound scanner, make sure that these images correspond to the patient whose identifier you entered into the ultrasound.
- The images to be exported must be 3D volumes of the ovaries of a patient that meets the requirements of use.
- Do not attempt to export screenshots or video from your ultrasound.
- The browser supported by the platform is Google Chrome version 100.0.4896.127 (and higher).
- For the correct representation of the results in OSIS Ovary, a screen of at least 14 inches with a minimum resolution of 1920 x 1080 pixels is required.
- OSIS Ovary is not a real-time service. Images exported from your ultrasound scanner will be queued to be processed on the server. Please note that the delay you experience when exporting images will depend on the internet speed contracted by your center.
- For the platform to work properly, the user is recommended to use a computer that meets the following minimum characteristics:
    - i3 processor or similar
    - 4GB RAM
- The correct functioning of all the features of the platform is not guaranteed when used from a mobile device (smartphone, tablet, etc.). It is always recommended to use the platform from a computer with the characteristics mentioned above.
- The user must always verify that the information in the reports that the platform generates matches the corresponding case information displayed on the platform.
- The use of the platform is intended exclusively in clinic for experienced professionals (doctors, nurses, or technicians) in the use of gynecological 3D ultrasound with transvaginal probe.
- The use of OSIS Ovary requires specific training in the use of ultrasonic equipment.
- The images obtained with the transvaginal ultrasound equipment must have an adequate quality, that is, contain the desired anatomy in its entirety, show contrast in the different parts of said anatomy and not be affected by high levels of noise or artifacts.

- The final evaluation of the results produced by OSIS Ovary should always be supervised by a doctor with competence in the area of fertility.
- In case of any eventuality, problem or query, the user will contact Fertoolity Technical Service through the email: info@fertoolity.com.
- The user must notify Fertoolity of any serious incident related to the product (info@fertoolity.com) as well as to the competent health authority, in this case, to the AEMPS.

1.6. Contraindications

There are no known contraindications of OSIS Ovary, nor undesirable side effects from its use.

1.7. Symbols

Symbol	Meaning	Reference
	Manufacturer	EN ISO 15223-1 ISO 20417
	Date of manufacture	EN ISO 15223-1 ISO 20417
	Consult instructions for use	EN ISO 15223-1 ISO 20417
	Electronic instructions for use to indicate on product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed paper form.	ISO 7000 - 3500
MD	Medical device	EN ISO 15223-1 ISO 20417

SN	Serial Number In the case of OSIS Ovary, the software platform version is provided	EN ISO 15223-1 ISO 20417
UDI	Unique Device Identifier	EN ISO 15223-1 ISO 20417
CE	CE symbol indicates compliance with MDR regulation 2017/745 for medical devices in Europe It is accompanied by the number of the Notified Body. The OSIS Ovary label shows XXXX as it does not yet have the approval of the Notified Body. We are in process.	MDR 2017/745

1.8. Nomenclature

- **OSIS**: Online System for Image Segmentation
- **3D**: Three-dimensional
- **IP**: Internet Protocol
- **LMP**: Last Menstrual Period
- **ID**: Identification number of the patient
- **IVF**: In vitro Fecundation
- **AI**: Artificial Insemination
- **IVI RMA**: Valencian Institute of Infertility Reproductive Medicine Associates
- **SIVIS**: IVI Information System
- **COS**: Controlled ovarian stimulation

2. OVERVIEW

OSIS Ovary is an online web platform for use linked to clinics specialized in reproductive medicine, which provides automatic segmentation and objective anatomical measurements of the different ovarian follicles (folliculometry) from the reception of ultrasound volumes (3D) of the ovaries, so that medical staff can use this information for monitoring controlled ovarian stimulation (COS) of patients during in vitro fertilization (IVF), oocyte vitrification or artificial insemination (AI) cycles, making folliculometry processes more flexible in clinics, as well as clinical decision-making.

Folliculometry is a procedure that involves periodic transvaginal ultrasounds to monitor the growth of follicles in the ovary, measure follicular size to monitor COS. It is a simple and routine procedure, performed between 2-6 times during each cycle of ovarian stimulation. Currently, manual folliculometry is performed by the gynecologist in order to count the number of follicles per ovary and measure the diameter of the follicles, one by one (manual measurement of the follicle). This technique is considered the Gold-Standard in clinical practice.

OSIS Ovary allows the automation of ovarian follicle measurement work, significantly reducing the hours used by clinicians in the treatment and analysis of these images, providing repeatable anatomical measurements of the different ovarian follicles objectively and that can be used from any 3D ultrasound equipment no matter where you are.

The automatic segmentation of ovarian follicles is carried out using an Artificial Intelligence model (Deep Learning). From this segmentation, OSIS Ovary calculates the number of follicles detected in an ovary and their average diameter.

OSIS Ovary is hosted on IVI RMA's central servers in Valencia in a dedicated facility under the supervision of the technical team and is designed to receive remotely (through the internal network between IVI clinics) Cartesian volumes captured with endocavitary 3D probes – usually for transvaginal use of General Electric Healthcare's Voluson Series ultrasound machines, via encrypted IP connection with Ethernet network cable.

OSIS Ovary incorporates an alert registration system, which activates alarm messages for the user when the ultrasound volume has not been correctly received, determining the specific cause detected and thus facilitating its correction or solution of the problem.

OSIS Ovary is equipped with a manual quality control system, which allows medical personnel to verify an adequate assessment of the ultrasound volumes received, as well as to manually report and correct those that have not been processed correctly.

OSIS Ovary is designed to work with Cartesian ultrasound volumes stored (prior to being exported) on the local hard drives of General Electric Healthcare's Voluson Series ultrasound machines. A copy of each volume exported to OSIS Ovary will also be saved on the OSIS Ovary server. This will make possible subsequent reviews of the ultrasound information remotely by the user or by Fertoolity Technical Service, if deemed necessary.

3. INSTALLATION

OSIS Ovary is distributed as a web platform and does not require installation on your computers. Similarly, no process is needed to uninstall it either. If you wish to cease the use of OSIS Ovary and have your data deleted, please contact Fertoolity team by sending an email to info@fertoolity.com.

Both the server and the storage devices are deployed in the dedicated facilities of the IVI RMA Group in Valencia. The user interface and software required to process ultrasounds sent to OSIS Ovary from ultrasound scanners are installed on the server. This allows users (who are authorized) to access remotely at any time and from anywhere as long as they are using a computer with the minimum requirements within the IVI RMA Group network. In this way, patient data is kept anonymous and stored in a secure environment.

Fertoolity team will be responsible for deploying OSIS Ovary in its center so that all users will always have access to the latest version of the software, not having to worry about software updates.

Likewise, Fertoolity team will notify all users of each update by means of an email with all the changes and a link to the user manual.

3.1. Requirements

To be able to use OSIS Ovary you need at least:

- A General Electric Healthcare Voluson Series ultrasound scanner
- A personal computer with a screen of at least 14 inches 14 inches and a resolution of at least 1920 x 1080 pixels that has an Intel i3 processor or higher and at least 4 GB of RAM.
- A browser and an Internet connection.
- All the aforementioned equipment must be connected and have authorized access to the IVI RMA Group network.

Once the medical staff has been discharged by Fertoolity Technical Service, you will receive an email notification to access the online web system. In this email the user will be provided with a link to select their secure password before accessing the platform. This ensures that no one else has access to each user's credentials at any time.

SIVIS users will be able to access the platform from SIVIS itself without having to generate another password. However, they need to be authorized to access OSIS Ovary, from the SIVIS portal.

Fertoolity Technical Service will configure the ultrasound scanner(s) of your clinic to obtain a correct connection and export of ultrasound volumes to the OSIS Ovary platform.

Fertoolity team is not responsible for the periodic maintenance of ultrasound machines, probes, computer equipment and network connections. Likewise, to ensure a correct result of the ultrasound volumes processed in OSIS Ovary, the clinical personnel authorized to perform ultrasound (doctors, nurses, or imaging technicians) must be

familiar with the technique of capture and export handling of ultrasound volumes, being able to request from Fertoolity an additional specific training for this purpose.

3.2.   How to get started

To start using OSIS Ovary you will need Fertoolity technical team to configure your ultrasound machine so that you can export volumes to the platform.

Likewise, Fertoolity team will register a user with whom you can access the platform. To do this, you must provide Fertoolity team with a valid email to which a link will be sent so that you can enter a password before accessing the platform.

4. WORKFLOW

The workflow in OSIS Ovary begins with the export of a case from a specially configured ultrasound machine.

After the ultrasound machine is configured, the steps to export a case to OSIS Ovary are as follows:

Load the patient from the SIVIS agenda as we do to pass the ultrasound images: *with the right mouse button, we select 'send to ultrasound scanner' and select the ultrasound scanner from which we are going to do the scan.*
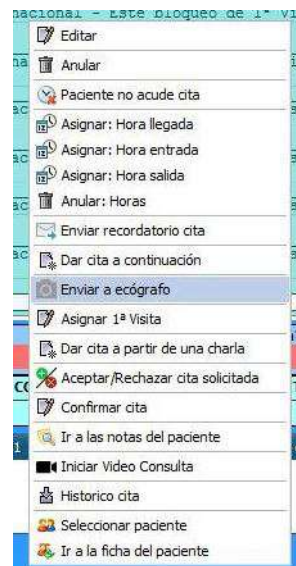

Figure 1. Agenda options in SIVIS.

ID	AE Title	Clínica	Nombre	
86	ECOVLC01	7 - IVI Valencia	ECOVLC01 [192.168.168.199]	››
87	ECOVLC02	7 - IVI Valencia	ECOVLC02 [192.168.168.198]	››
88	ECOVLC03	7 - IVI Valencia	ECOVLC03 [192.168.168.197]	››
89	ECOVLC04	7 - IVI Valencia	ECOVLC04 [192.168.168.196]	››
90	ECOVLC05	7 - IVI Valencia	ECOVLC05 [192.168.168.188]	›
91	ECOVLC06	7 - IVI Valencia	ECOVLC06 [192.168.168.194]	›
92	ECOVLC07	7 - IVI Valencia	ECOVLC07 [192.168.168.186]	›
93	ECOVLC08	7 - IVI Valencia	ECOVLC08 [192.168.168.192]	›
94	ECOVLC09	7 - IVI Valencia	ECOVLC09 [192.168.168.205]	›
95	ECOVLC10	7 - IVI Valencia	ECOVLC10 [192.168.168.189]	››
96	ECOVLC11	7 - IVI Valencia	ECOVLC11 [192.168.168.191]	››

Figure 2. Ultrasound worklist.

After one minute (maximum) the data will be available on the ultrasound machine.

To select the patient, we have sent from SIVIS, press the button on the two dolls (figure 3). Then we select worklist (*Lista de trabajo*) (figure 4).

Figure 3. Patient button.

Figure 4. Worklist selection screen.

We select the patient and start the examination. We will see that the first and last name, date of birth and patient ID have been loaded on the ultrasound scanner.

Now we have to enter manually the **last menstrual period (LMP)**. To do this, select the Gyn configuration (figure 5) in the left side menu shown in the figure.
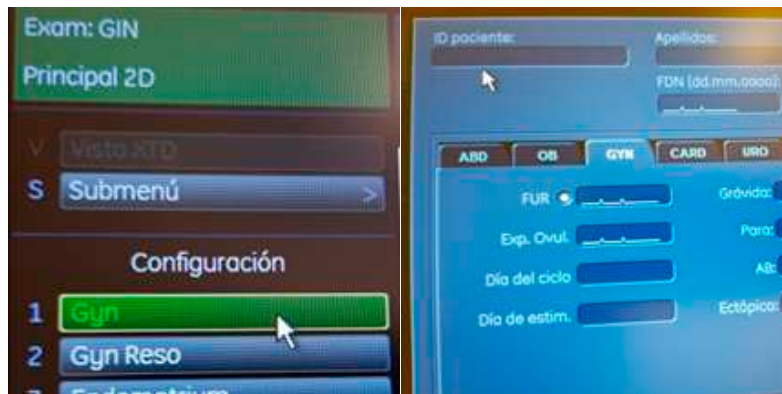

Figure 5. GYN menu for entering the LMP.

Next, let's capture the 3D volumes. **First right ovary and then left ovary**. To change ovary, we use the lever intended for this purpose. Open the corresponding menu by pressing the 3D button. With the corresponding levers, we select the maximum quality and the sufficient capture angle so as not to leave structures out of the volume. After performing the sweep, we store it as *a volume* with the **P1** button configured for it.
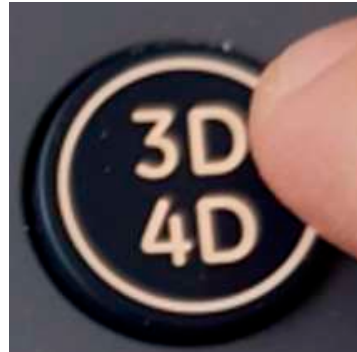

Figure 6. 3D volume capture button.

Figure 7. Ovary selection lever.

Finally, we will export the information. To do this, click the **Archive** button.

Figure 8. File button.

Select the volumetric files of the two ovaries and choose the **Export** option from the left vertical menu.

We must select the **NW2** Unit in case of the ovaries and the **NW3 Unit** in the case of the uterus.
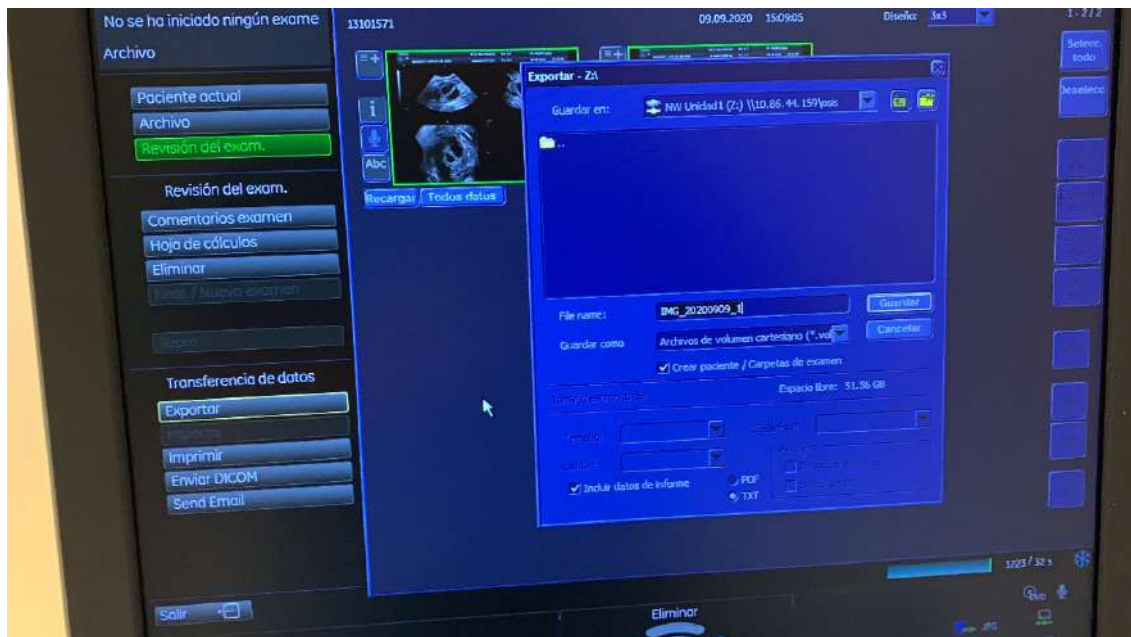

Figure 9. Export screen.

If there is the option **'create patient / examination folder'** we must mark it and click on **Save** and wait a few seconds until the export is made.

Clicking on **Exit** we return to the starting point to continue with the next patient.

Once you have exported all the cases you need, you can access the platform with your user to review the results as indicated in sections 5 and 6 of this manual.

5. LOGIN

The user has two ways to access the platform:

1) Logging in from the login screen: http://osis.ivi.org
2) accessing from the SIVIS patient view.

In both cases, your user must be registered on the platform. For this you can contact the person in charge of your center or Fertoolity team. In this view you can change the language (Spanish, English) before identifying yourself as a user. After being identified, the language selected by the user in their last session will be maintained.
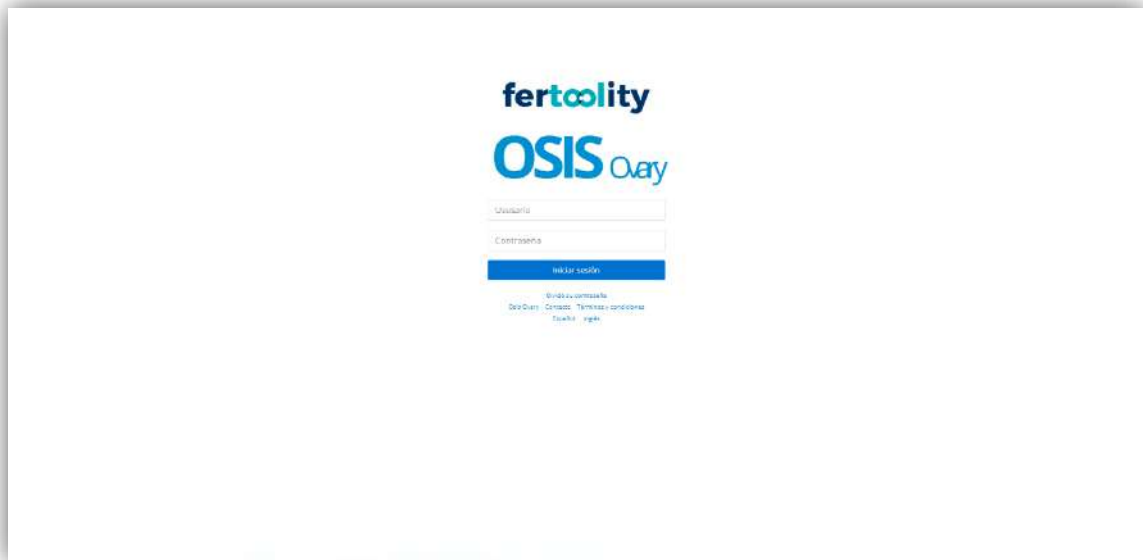

Figure 10. The login screen.

6. ACTIONS YOU CAN PERFORM WITH OSIS Ovary

6.1.   Consult and/or accept the terms and conditions

You can access the terms and conditions before logging in by clicking on the "Terms and Conditions" link on the login screen (figure 10).

Once you have identified yourself as a user, if it is the first time you access, the platform will direct you to the terms and conditions screen (figures 11 and 12) where you must read and accept the terms and conditions in order to use the platform. You will not be able to use any of the functions of the platform if you have not accepted the terms and conditions. In the event that these terms change, it would be necessary to read and accept them again in order to use the platform.
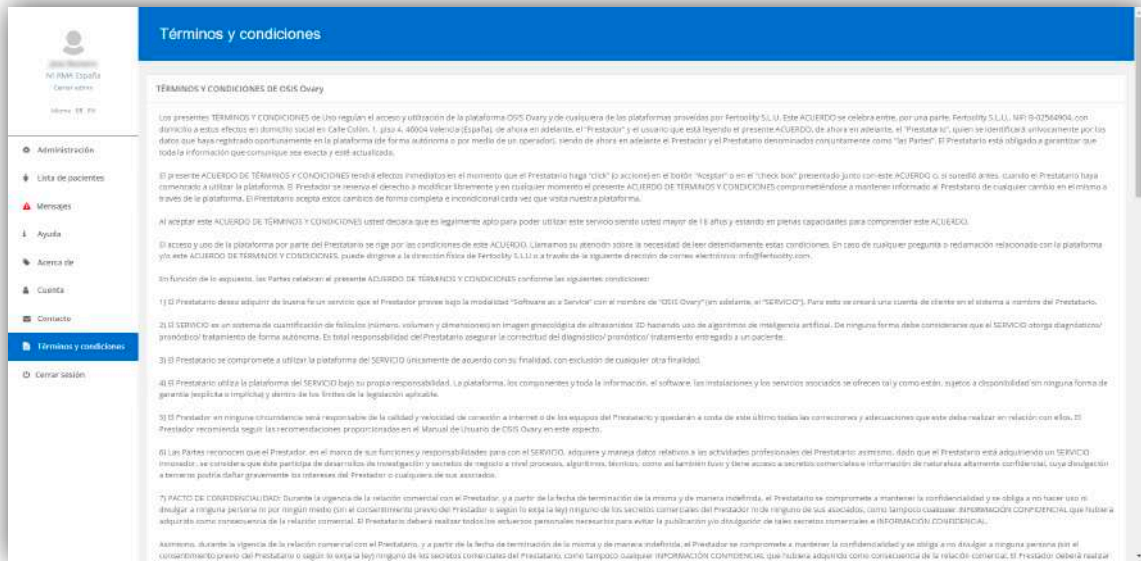
Figure 11. Screen of terms and conditions.

Figure 12. Terms and conditions screen (acceptance box).

You can access the terms and conditions screen at any time by clicking on the side menu option "Terms and conditions" (figure 13). Terms and conditions are available in Spanish and English.
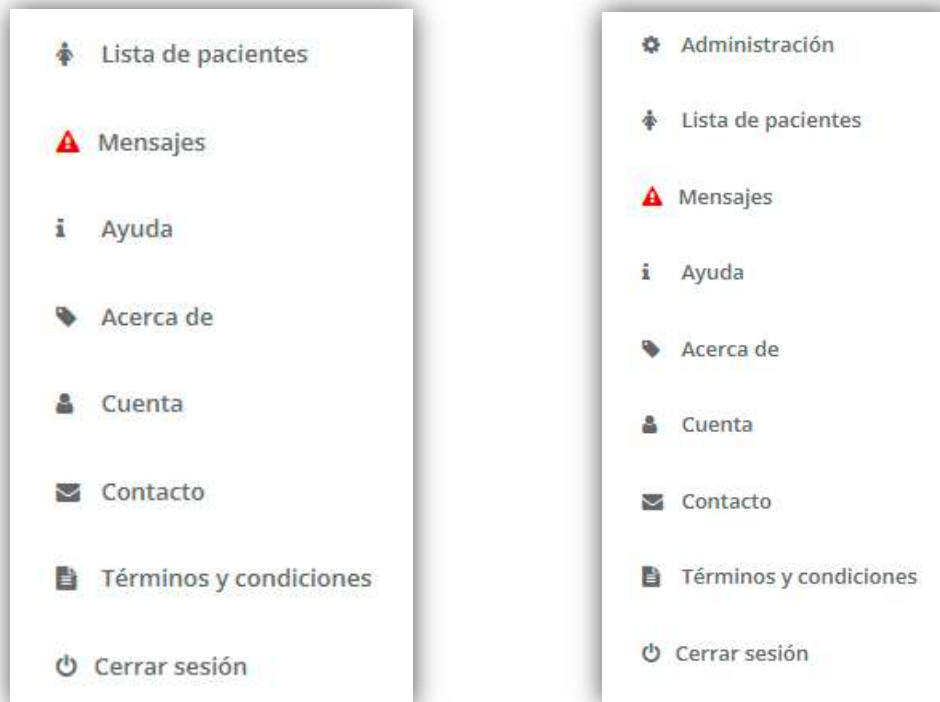
Figure 13. Side menu, on the left the menu for basic user, on the right, the menu for center admin.

6.2. Check the product label

You can check the product label before identifying yourself as a user from the login screen by clicking on the "OSIS Ovary" link (figure 10).

The elements that appear on the label are detailed in the Symbols section of this User Manual (section 1.7).

In addition, you can find:

- the UDI, which is a traceability number of medical devices and identifies this specific software with its UDI-DI (01), and UDI-PI (11) and (21).
- a QR code or DataMatrix in which the UDI of the product has been encoded for easy access and
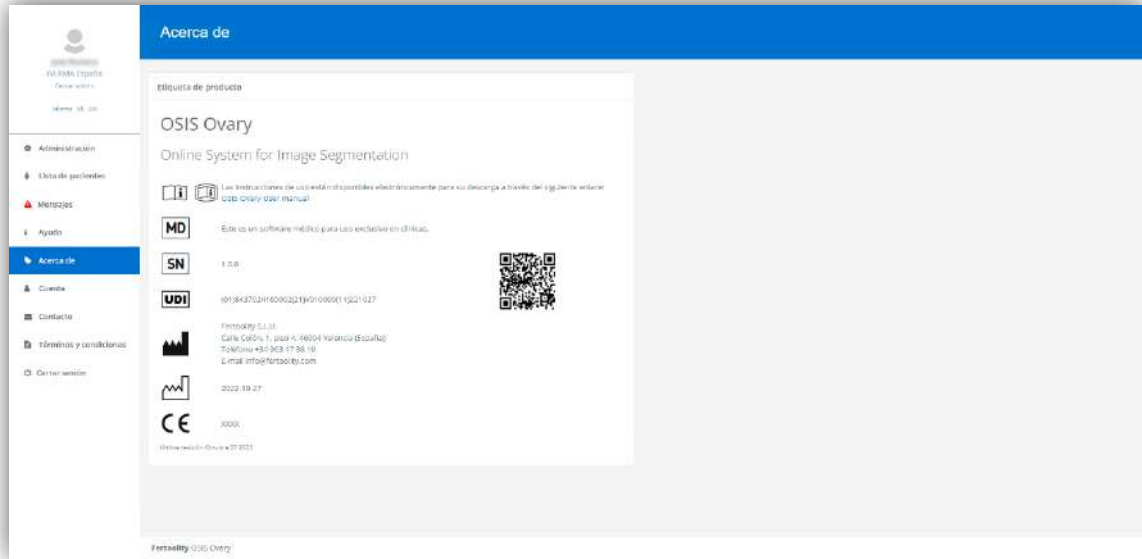- a link to the latest revised version of the OSIS user manual.

Figure 14. Product label screen.

Once identified as a user, you can access this screen by clicking on the side menu option "About" (figure 14).

6.3. Contact the OSIS Ovary team

You can contact the OSIS Ovary team by sending an email to info@fertoolity.com. You can easily access this email address by clicking on the "Contact" link on the login screen (figure 10) or on the "Contact" option of the left menu (figure 13).

6.4. Download the user manual

You can download the user manual once you have logged in from the Help (figure 15) or Product Label (Figure 14) screens which you can access from the options in the side menu (figure 13) "Help and About", respectively.
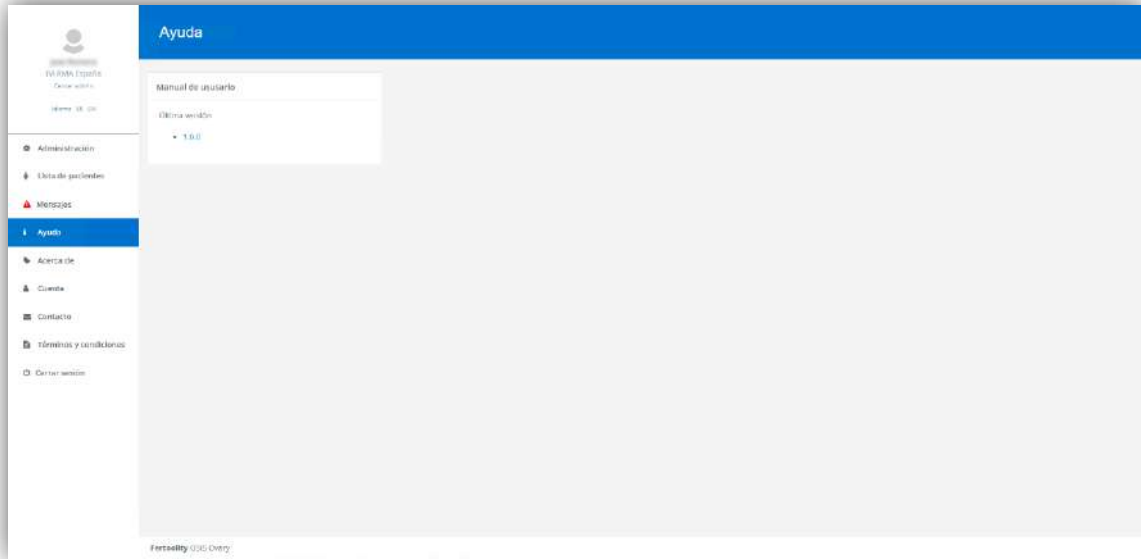
Figure 15. Help screen.

6.5.   Change your password and view account information

You can change your password from the Account screen (figure 16), in the "Change password" section. You can access it from the side menu option "Account".
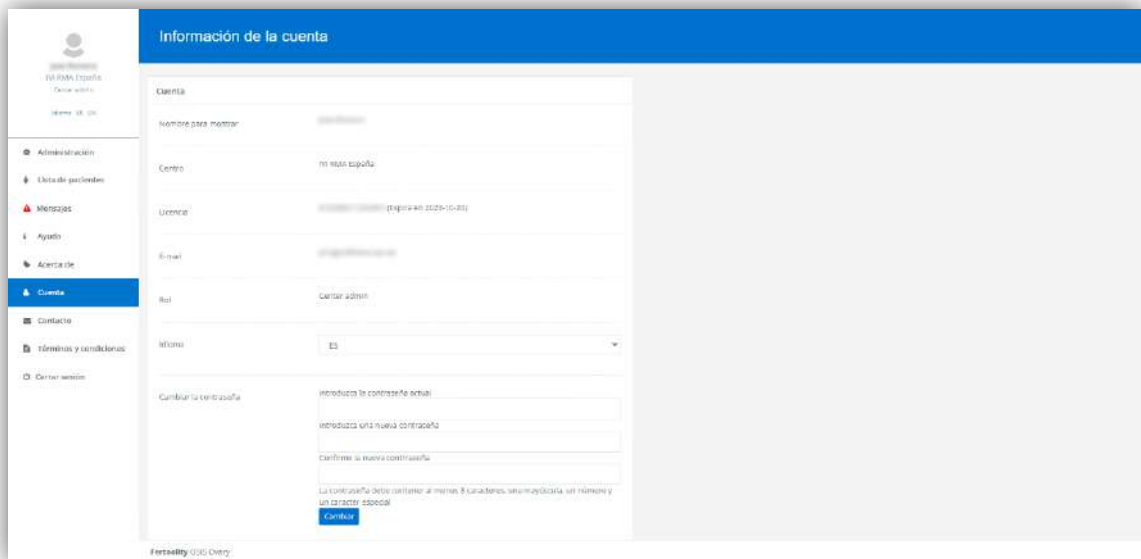

Figure 16. The user account information screen.

In addition, on this screen, the user will be able to consult the email with which he/she is accessing the platform (e-mail), the center in which he/she has been registered (Center), the license through which he/she accesses the service and its status (License), the level of privileges of his/her user (Role) and the current language selected and change it (Language).

6.6.   Recover your password

If you have forgotten your password, you can set up a new one again by clicking on the "Forgot your password" link on the login screen (figure 10). The platform will take you to a new screen to enter your email account with which you identify yourself in the system (figure 17).
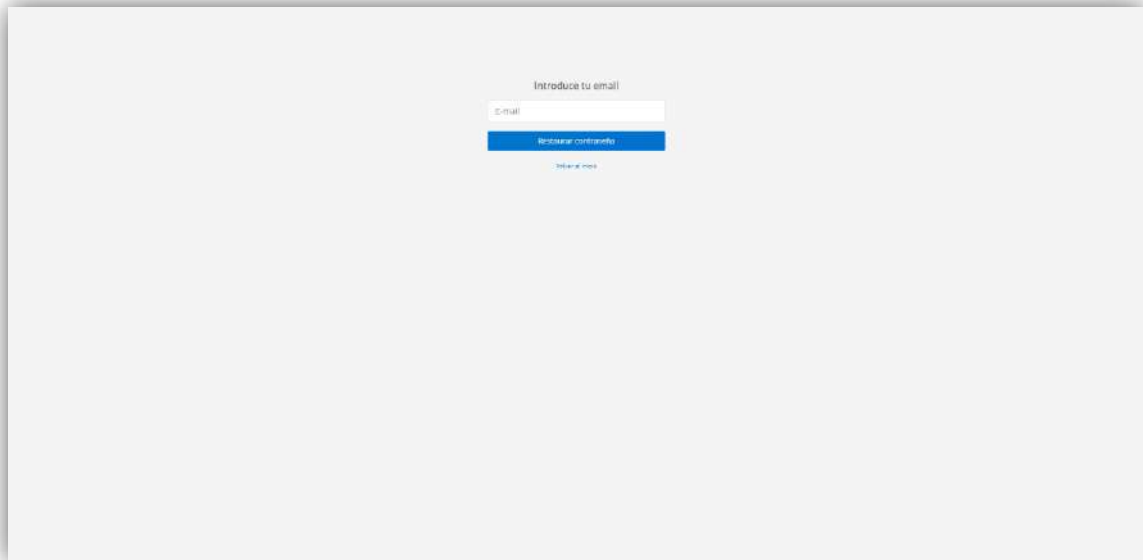

Figure 17. Screen to start the password recovery process.

Enter your email and click on the "Reset password" button. You will receive an email with a link to access the screen where you can enter a new password (figure 18). Please note that this link will only be valid for 15 minutes.
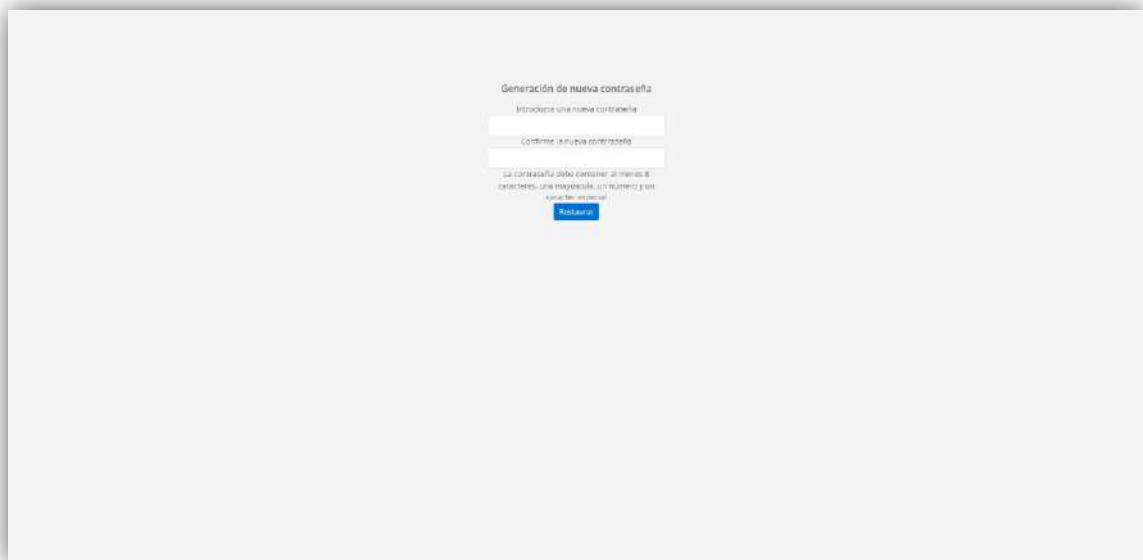

Figure 18. The password reset screen.

6.7.   Process a case

To process a case, you must follow the steps described in section 4 (WORKFLOW).

6.8.   View the results of a case

If you do not have a user with center admin privileges, you can only directly access a patient's report from SIVIS through a link in the application itself. If you need help in this regard, you should contact the staff responsible for SIVIS.

If you are responsible for center (center admin), you can access the list of patients (figure 19).
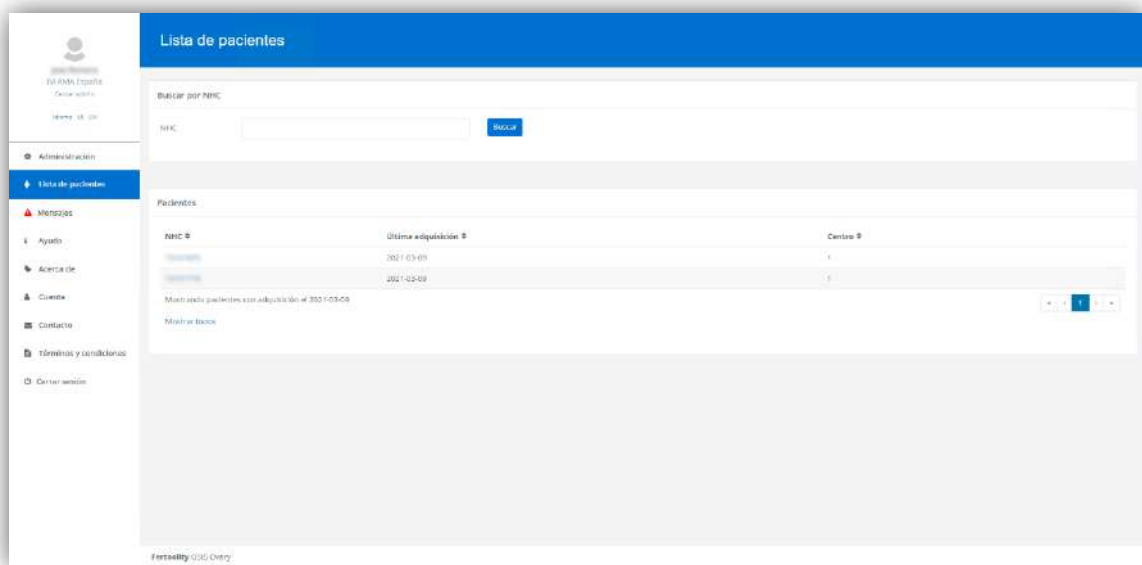
Figure 19. List of patients.

From this screen you can navigate in the patient table to find the patient ID of the patient you want to consult or enter the ID in the "Search by ID" box and click on the "Search" button.

You can enter the patient's full ID (8 digits) or enter it partially so that the platform searches for all those that begin with the digits entered in the box.

Once the patient is located, click on their ID to access the patient report screen (figure 20).

Figure 20. Patient report screen.

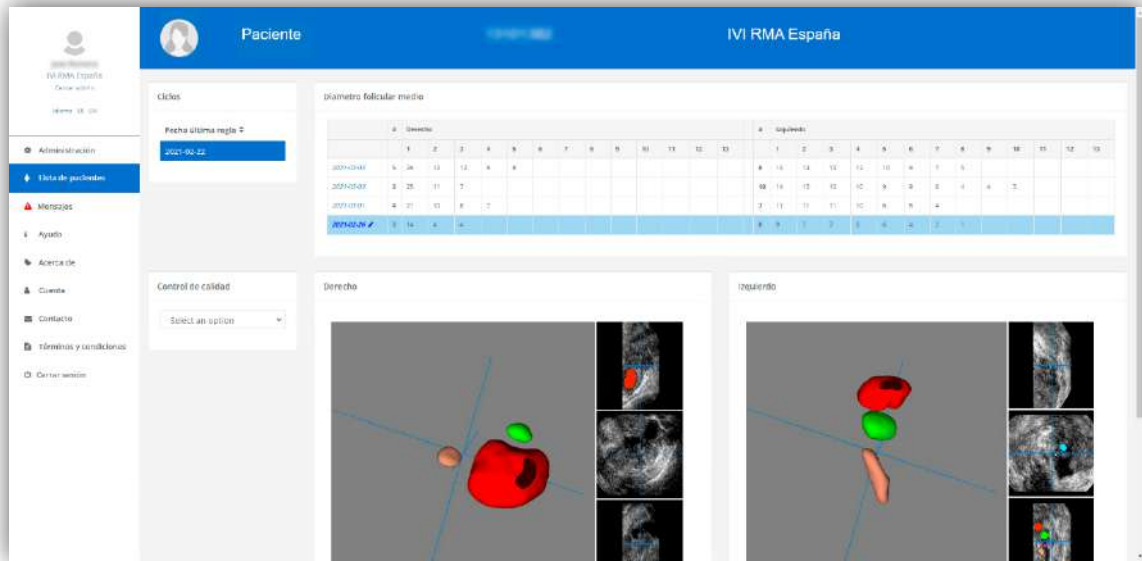On the patient report screen you can select a stimulation cycle (if there is more than one) in the upper left "Cycle" box by clicking on the Last Menstrual Period.

Once the stimulation cycle has been selected, a table will be shown (referring to the average follicular diameter) with different acquisitions (ultrasound images) that have been made to the patient during the cycle to date. In this table, each row corresponds to an acquisition in which the average diameters of each follicle are shown. The "Right" column corresponds to the right ovary, the "Left" column corresponds to the left ovary and the "#" column indicates the number of follicles detected in that ovary, ordered from highest to lowest (from left to right).

You can click on the acquisition date (figure 21) to select the one you want to display (the platform selects the last one by default). Once selected, the platform highlights the row in blue and shows the automatic segmentation of the patient's follicles in the lower boxes "Right" and "Left" that correspond to the patient's two ovaries.
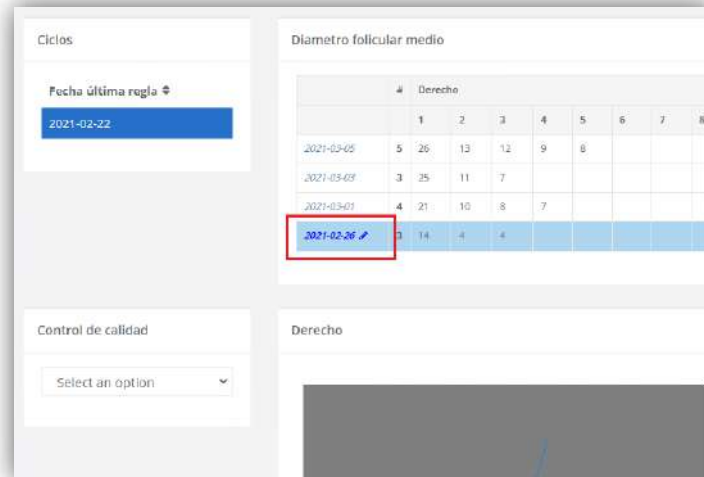
Figure 21. Selected acquisition date.

The multiplanar viewer (figure 22) shows in its main view the 3D representation of the automatic segmentation of the follicles in the ovary (you can move it by clicking and dragging the mouse over the 3D representation itself). In addition, it shows the 3 Sagittal, Coronal and Axial acquisition planes with automatic segmentation of the follicles superimposed to the original acquisition. You can swap these drawings in the main view by clicking on the "Swap view" button in the viewfinder.
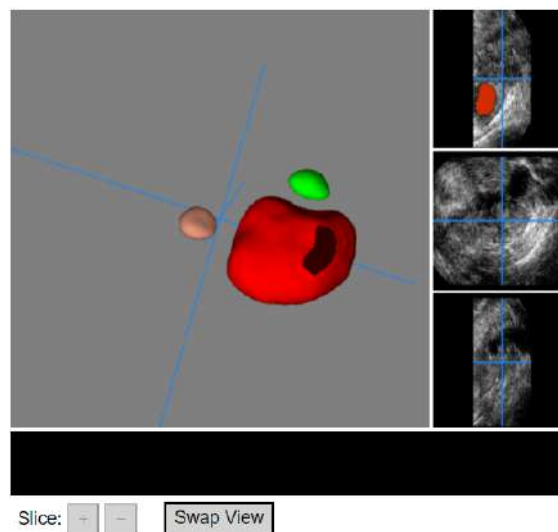
Figure 22. Multiplanar viewfinder.

With the mouse over one of the three acquisition planes, you can use the mouse wheel to scroll through volume slices. You can also scroll through the drawings using the "+" and "-" buttons in the viewer (figure 22) when an acquisition plane is being displayed in the main view. The blue axes superimposed on the acquisition planes and represented in the 3D view show the same pixel so that the user can establish a correspondence between the 4 views.

6.9. Perform quality control of a case (Exporting data to SIVIS)

On the patient report screen, after selecting a stimulation cycle in the "Cycle" box and an acquisition (ultrasound) in the "Mean follicular diameter" table, you can select one of the options in the lower left box "Quality control" (figure 23) concerning the quality of the ultrasound images and the results.
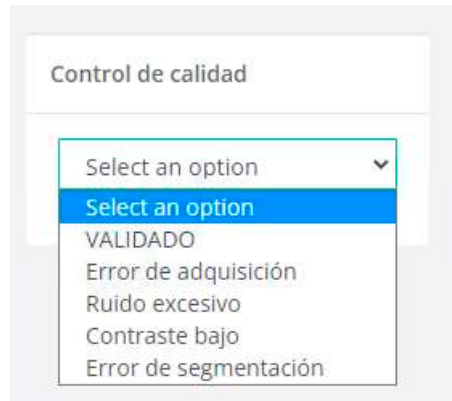

Figure 23. Quality Control options.

If you conclude that the images (ultrasounds) have a sufficient quality, the automatic segmentation of the follicles is correct and the average diameter values are adequate, you can select VALIDATED in the quality control menu to approve the results and have SIVIS proceed to read them after which a box will appear with the title "Export to SIVIS" informing of the reading status of these:

- Pending: The data has been approved and can be read by SIVIS.
- Exported: SIVIS has read the data.
- Export error: SIVIS could not read the data.
- It does not pass the QC: The user has not approved the data and SIVIS will not read it.

If, on the other hand, you feel that the results are not correct due to poor image quality, you can select one of the following options from the quality control menu to record the subject. Figure 24 shows examples of images without sufficient quality:

- VALIDATED: Both the segmentation and the values of the diameters are correct.
- Acquisition error: In case any of the images (ultrasounds) does not contain an ovary.
- Excessive noise: In case any of the images (ultrasound) present too much noise to be able to distinguish the follicles.
- Low contrast: In case any of the images do not present enough contrast to distinguish the follicles.
- Segmentation error: If the quality of the images is adequate but the automatic segmentation is incorrect, you can consider making a manual correction of the values in the table (explained in the following section).
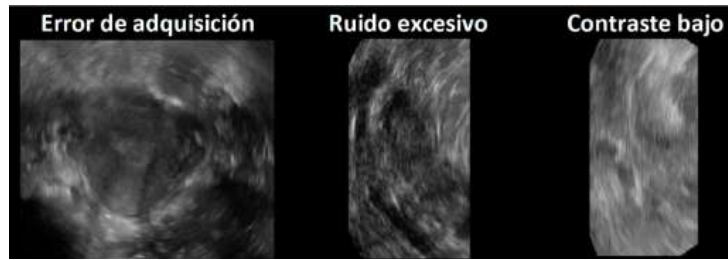
Figure 24. Example of low-quality images. From left to right, image of a uterus, image with too much noise, image with too little contrast.

6.10. Manually correct the folliculometry of a case

In the event that the values generated by OSIS Ovary are not adequate, you can consider performing a manual correction of these.

To do this, first select the acquisition you want to modify (make sure it is highlighted in blue as shown in figure 20). Acquisition date will appear in bold and next to it, you will see the icon of a pencil indicating that the values can be edited.

Click on the pencil and you will be taken to the manual correction screen (figure 25).
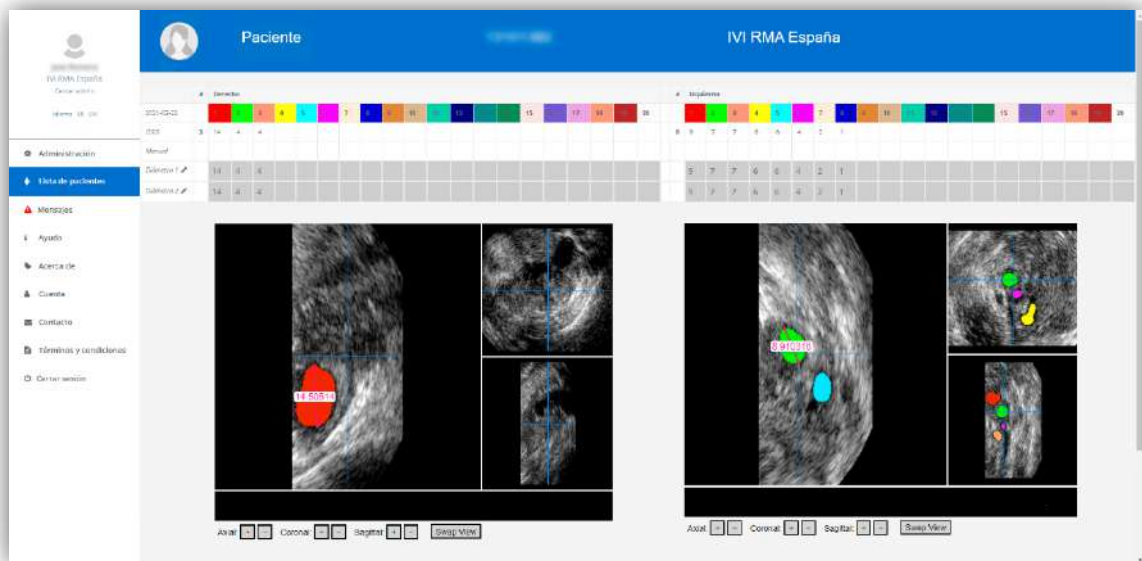
Figure 25. Manual folliculometric correction screen.

The screen is similar to the patient results report, but, this time, in the table above where the average diameters are shown, each follicle is assigned a color that matches that of the multiplanar representation that appears below showing the three planes of acquisition (axial, sagittal and coronal) with the segmentation superimposed and a ruler with two adjustment points.

The table of average diameters has five rows. The first indicates the number of each follicle and its color. The other rows indicate the following information:

- OSIS: Displays the diameters obtained automatically by OSIS Ovary.
- Manual: Displays the values of the last manual correction if any. When you access the editor again after saving your manual correction, the result will be remembered in this row.
- Diameter 1 and Diameter 2: These are editable boxes that, when starting the screen, show the automatic values obtained by OSIS Ovary to facilitate the task.

On this screen you can perform diameter measurements manually. The steps are the following ones:

1. Identify the color of the follicle that needs to be corrected (for example, red).
2. Navigate in the viewer until you locate the follicle to be measured (figure 25).
3. Select a slice where the diameter can be clearly measured (figure 25).
4. Adjust the ends of the ruler by dragging them to the contour of the follicle to be measured (figure 25).
5. Note the value provided by the ruler in the Diameter 1 box of the follicle to be corrected.
6. Repeat steps 3, 4 and 5 to obtain another measurement that you will enter in the box Diameter 2 of the follicle to be corrected.
7. When you have written down the measurements for all the follicles you want to correct, click on the "Save" button at the bottom (figure 27)

You should write down two measurements for each follicle you want to correct. If you leave a measurement to be noted, the system will remind you.

If you want to remove a follicle (for example, green), leave your Diameter 1 and Diameter 2 boxes blank as shown in figure 26.

Figure 26. Blank boxes to remove a follicle.

When you click save, the system will read the data entered in the Diameter 1 and Diameter 2 boxes, compute the average value for each diameter and store it to display it in the patient report.
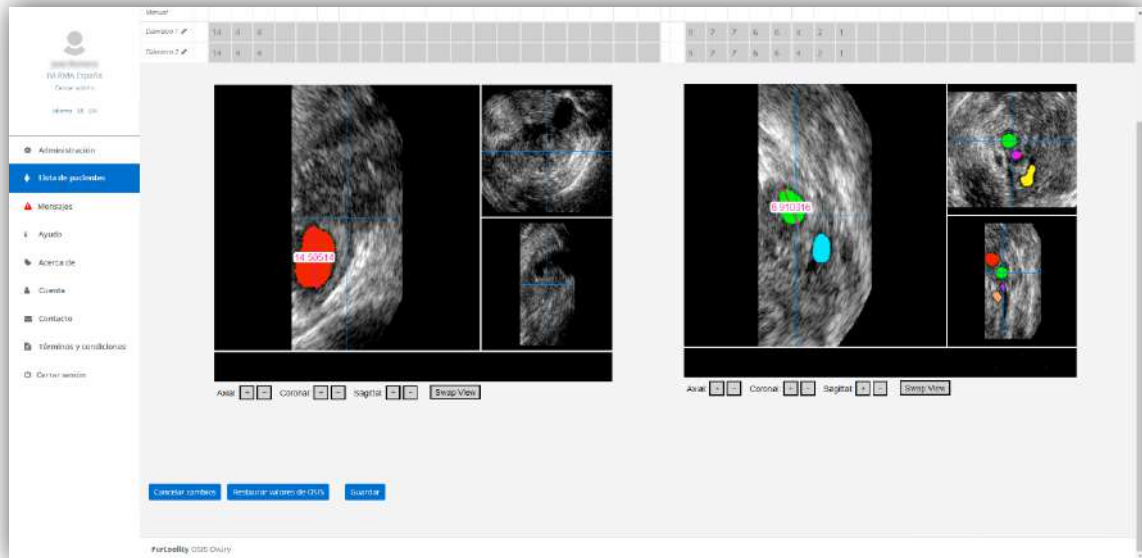
Figure 27. Manual folliculometric correction screen (buttons).
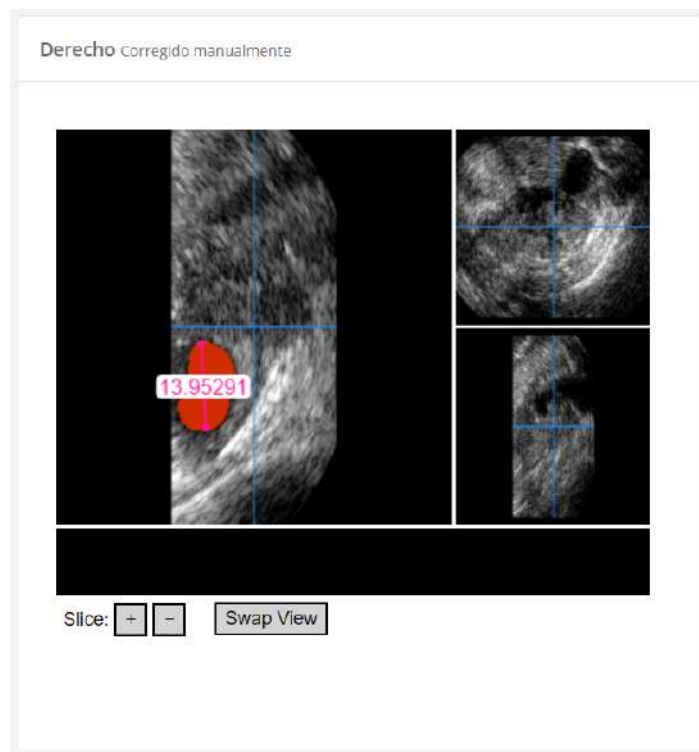

Figure 28. Multiplanar viewer in the patient report after manual correction.

If during the correction process you want to discard the changes made and return to the patient report, click on "Cancel changes" button.

If you want to reverse the values of a manual fix that has already been saved and recover the automatic values of OSIS Ovary, click on the "Restore OSIS values" button.

6.11. Manage your facility's clinics and users (Center Manager Only)

If you are the center administrator, a new option will appear in the side menu (figure 13) with the name "Administration" (figure 29) in which you can consult the license contracted by your   center in the upper table "License", the ultrasound scanners discharged in the system in the table "List of clinics", and the users who have been given access to the platform in the table "List of users".
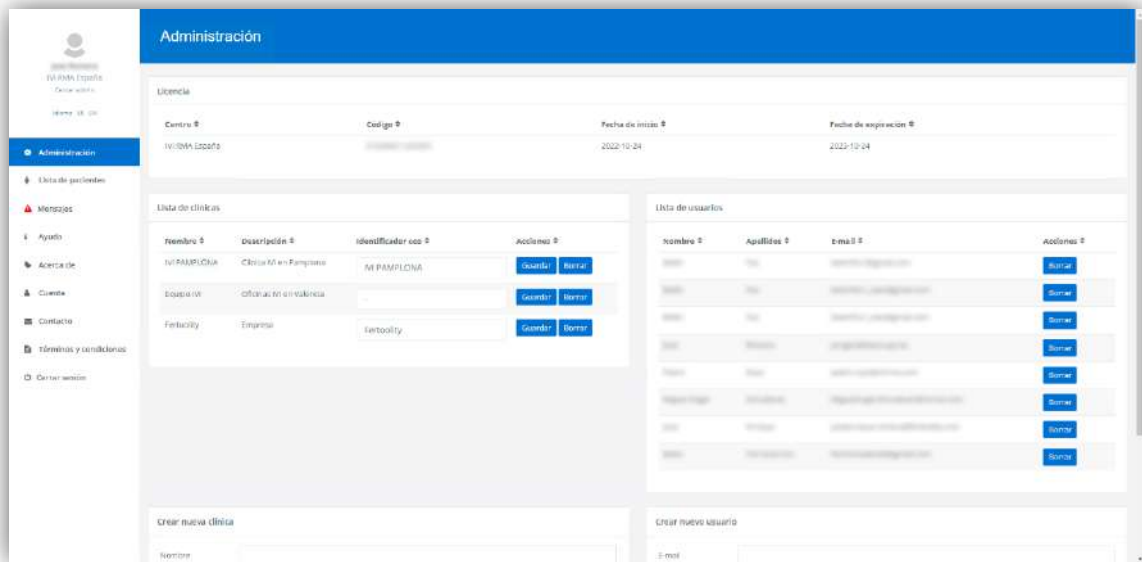
Figure 29. Administration Screen.

In the "List of clinics" table you can modify the text with which the ultrasound scanners are identified on the platform by writing in the "Ultrasound identifier" box and clicking on the "Save" button. You can also delete ultrasound machines by clicking on their corresponding "Delete" button.

You can also delete users by clicking on their corresponding "Delete" button in the "User list" table.

If you need to assign center administrator privileges to one or more users, you can contact Fertoolity team by sending an email to info@fertoolity.com.

You can register new ultrasound scanners and users using the "Create new clinic" and "Create new user" menus at the bottom by filling in the fields requested (figure 30).

Figure 30. Administration screen (Discharge of ultrasound scanners and users).
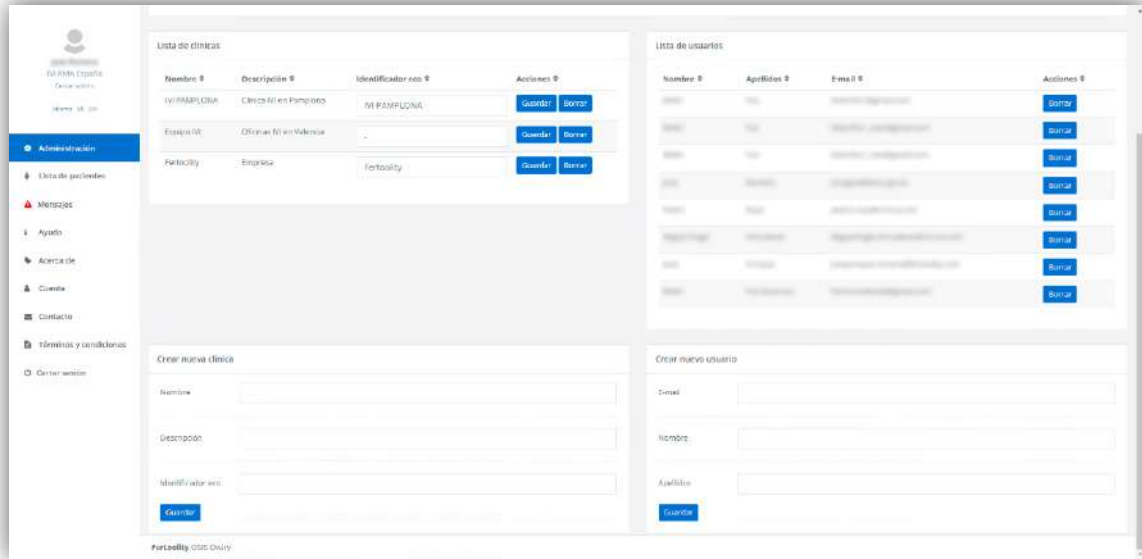
Please note that when you create a new user, they will receive an email to activate their password that will only be valid for 15 minutes. If you exceed the activation time, contact Fertoolity team by sending an email to info@fertoolity.com

6.12. Log off

To log out, click the "Logout" button in the side menu (figure 13). We strongly recommend that you do not leave your work team without logging out of the platform.

This option is valid whether you have accessed from SIVIS or directly from the Login screen.

7. POSSIBLE ERRORS

It is possible that, during the process of exporting or generating results, an error occurs.

OSIS Ovary will register these errors with all the information that has been possible to be collected and it will show them to the user on the platform, in the "Messages" section available in the side menu (figure 31).
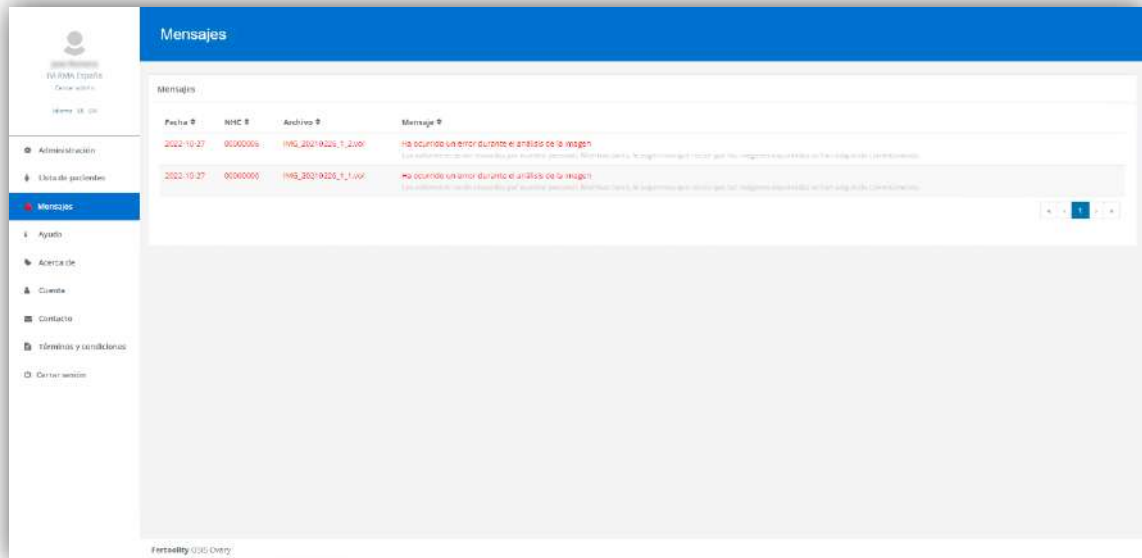
Figure 31. Error message screen.

When OSIS Ovary detects an error, the icon in the "Messages" section will appear in red. Click on the "Messages" option to access and read the errors that may have occurred.

The "Messages" table will display a list of the latest unread error messages. Once read, when you leave the screen, they will not appear again, and the side menu icon will go from red to gray.

For each error we observe the following fields:
- Date: The date the error was generated.
- ID: ID of the patient whose case generated the error (if it has been possible to recover it).
- File: Name of the file that generated the error.
- Message: Description of the error in red and a recommendation to fix the problem in grayed out.

If following the recommendations, the error persists, please contact Fertoolity team by sending an email to info@fertoolity.com indicating all the error data listed in the table.

The following errors are the possible ones that OSIS Ovary is able to detect:

1. **File cannot be** processed: OSIS Ovary has received a file in a format that cannot be processed. The user will have to re-export the case from the ultrasound machine following the instructions in the manual.
2. **Incorrect ID for the received file**: The system reports the receipt of a volume with an incorrect ID (without the eight digits it must contain). So, in these cases it is impossible to identify the patient. The way to solve it is by re-editing the volume in the ultrasound machine and reintroducing the correct ID and re-exporting the volume (previously saved) from the ultrasound machine again.

3. **No valid images found (images must be 3D volumes)**: The system reports incorrect format of files that can be processed by OSIS Ovary. In these cases, the user must re-export the ultrasound volumes again, but in .vol format.
4. **No acquisitions were found**: No ultrasound files have arrived in the OSIS Ovary system, but the associated data has. It can be due to two causes: either that the Internet connection has occasionally failed for a few seconds (and therefore the file is incomplete or corrupt and therefore not received) or that the option "create patient / examination folders" has not been selected prior to export, or the file if it has arrived well at OSIS Ovary, but it is located in the trash of the server, and therefore it is not indexable, and therefore not detectable. In these cases, the user must re-export the ultrasound volumes according to the manner explained above, as well as contact the clinic's computer maintenance services to verify that the network connections are working correctly.
5. **Patient data not included in the export**: The patient data has not arrived together with the exported image. In this case, the user must re-export the ultrasound volumes according to the mode explained above.
6. **Incorrect image name**: The images that have arrived at OSIS Ovary are not named correctly and, therefore, it is not possible to identify which corresponds to the right ovary and which to the left. You should contact your center manager or Fertoolity team to solve this problem.
7. **An error occurred during image analysis**: The process of handling the files and/or automatic analysis have failed. You should contact Fertoolity team to have the case reviewed carefully.
8. **The received ultrasound machine identifier is not registered**: OSIS Ovary does not have registered the identifier with which its ultrasound machine sends cases to the platform. This may be due to the fact that the configuration of your ultrasound machine has been modified or because your head of the center has not registered it. Contact Fertoolity team so they can review your case carefully.

It is possible that neither the exported ultrasound volume file nor the accompanying data reaches OSIS Ovary. In this case, OSIS Ovary will logically not be able to notify the user of this failure. Therefore, the user must consult the query agenda scheduled from SIVIS, to claim this scan if it does not arrive via OSIS Ovary. If this happens, contact Fertoolity team to identify the cause of the problem.

8. SECURITY MEASURES

- Authentication options

OSIS Ovary supports token-validated registration via email. Emails are reviewed for reuse, spam or malware emails, and other security issues.

- Secure credential storage

OSIS Ovary follows secure credential storage best practices by never storing regular passwords, and only non-reversible hashes are stored using SHA. Fertoolity employees cannot access credentials even in the event of a data breach.

- Secure credential policies

Each OSIS Ovary user sets their own password under the following password policies:

- At least 8 characters in length.
- At least one lowercase character.
- At least one uppercase character.
- At least one number
- At least one special character

All credentials are stored only as a hash, and it is not possible to access the full password.

- Security and authentication

Users are authenticated by their username (which matches their e-mail) and password. The password is transferred encrypted from the user's computer to the server making it impossible to recover it in case of interception of the transfer.

- Security vulnerabilities

Security issues like the top 10 OWASP vulnerability issues are covered by our use of frameworks and security measures such as peer policies and SQL injection protectors.

- Additional Product Security Features

Access privileges and roles

Access to data within OSIS Ovary is governed by access rights and can be configured to define access privileges. OSIS Ovary has several permission roles: user, center administrator.

User provisioning

The addition and editing of users can be done manually by Fertoolity team.

Transmission security

All communications with OSIS Ovary service provider servers are encrypted using industry-standard HTTPS. This ensures that all traffic between you and OSIS Ovary is safe during transit.

OSIS Ovary is designed to work integrated into the computer system of the IVI RMA Group clinics so, beyond the measures previously described, the IVI RMA Group implements protection mechanisms in the clinics' own network so that OSIS Ovary is not affected by security problems. These mechanisms are as follows:

1. Vulnerability analysis
2. 24h network monitoring
3. Resolution of incidents
4. Accident Response
5. Desktop stand
6. Alert system
7. Securing with Azure Sentinel

In addition to these measures, it complies with the set of good practices in the health sector recommended by the European Union:

1. General Data Protection Regulation (GDPR)
2. Network and Information Security Directive (NIS Directive)
3. European Union Cybersecurity Act

Perimeter protection system is also implemented:
1. Cisco Umbrella
2. Fortinet firewalls
3. Windows Defender
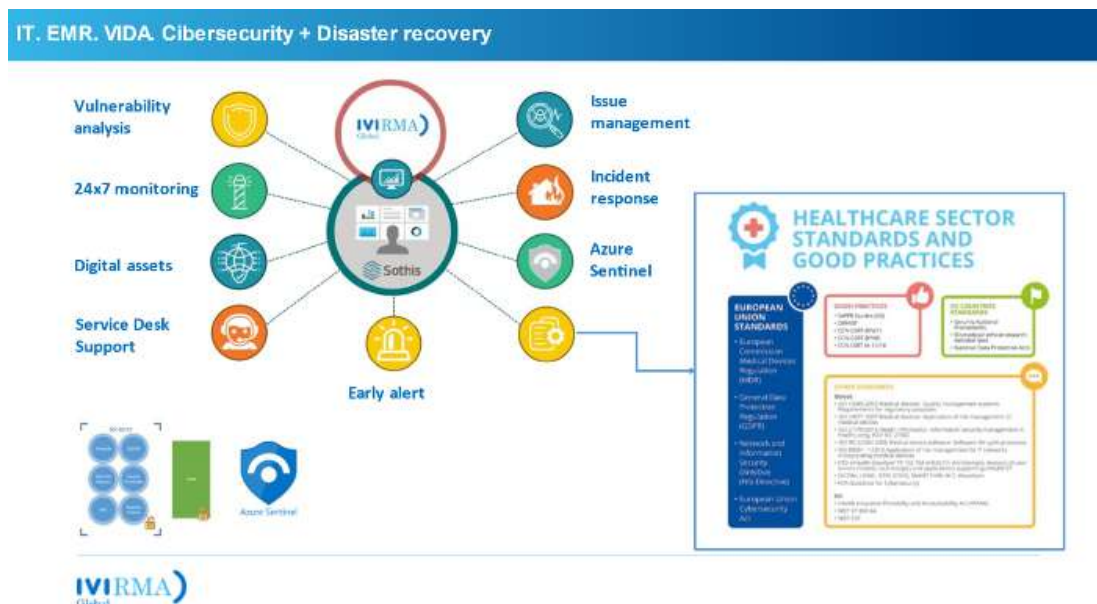4. Multi-factor authentication.

Figure 32. Outline of Cybersecurity measures implemented by IVI RMA Global

9. PERFORMANCE

9.1. Accuracy

OSIS Ovary provides an accuracy of 90% in terms of automatic segmentation and a concordance against Ground Truth in clinical practice of 80%, for the detection of follicles and the measurement of their average diameter.

To stay within this percentage, specific training in the use of ultrasound machines and special attention to the quality of the images acquired is required.

9.2. Quantification

OSIS Ovary calculates the number and size of the follicles of each ovary from their automatic segmentation using an artificial intelligence algorithm. It is this measurement process that we call quantification, and it is performed as follows:

- **Number of follicles**: The number of independent segmented elements in the ovary that is calculated from the grouping of pixels that correspond to the interior of a follicle that are adjacent to each other.

- **Mean follicular diameter**: For each follicle, in isolation, the coordinates of all the pixels that make up its contour are taken. For each of these pixels, the distance to the rest of the pixels of the contour is calculated and the maximum distance is taken. This is considered a diameter. Finally, the average of the maximum distances for each pixel is calculated.