Instructions for Use

Deep Capsule®

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Symbols

	Manufacturer
	Consult instructions for use (IFU)
	Medical device
	CE Mark and the Notified Body number
	Caution
	Catalogue number
	Unique Device Identifier
	Serial Number

1. Introduction

Name: Deep Capsule®

Reference: DeepCapsule_EU

Deep Capsule® is a non-invasive deep learning solution for automatic detection and differentiation of common findings in Capsule Endoscopy (CapE) images.

There are several clinical benefits provided by the Deep Capsule® technology, highlighting the following:

- Cost-effective technology, saving valuable resources and time.
- Faster small bowel lesions detection and differentiation.
- Decreased risk of overlooking clinically relevant lesions.

In summary, this technology is of relevant interest in the global evaluation of the small intestine mucosa, with particular importance in patients with suspected middle gastrointestinal bleeding, inflammatory bowel disease and digestive oncology.

2. Intended Purpose

Deep Capsule® is a non-invasive deep learning software driven by artificial intelligence (AI) intended to identify and differentiate normal mucosa and small bowel lesions in different images from capsule endoscopy videos (CapE). It is intended to be used by Digestive Health Clinicians (DHCs) with expertise in small bowel capsule endoscopy, affiliated with hospitals or point-of-care centers with Deep Capsule® software, and trained in the use of this technology.

3. Indications

Deep Capsule® is indicated to be used as an aid in identifying and differentiating lesions in the small bowel mucosa. It is intended to detect lesions in images obtained by CE, of patients aged 18 or above that have a suggestion of small bowel disease.

Deep Capsule® is not intended to replace clinical decision-making.

4. Contraindications

It is contraindicated to use the Deep Capsule® in the analysis of CapE exams that, for any reason, failed to reach the small bowel or did not record any small bowel segment. The use of Deep Capsule® is also contraindicated when good cleansing of the small bowel has not been achieved before the CapE exam.

In case the video is not uploaded correctly, either by having corrupted segments or by having a wrong format, they will not be analysed and will be removed from the user account. This event of malfunction will be logged in the system and reported if the user chooses to.

5. Target Population

Deep Capsule® is intended to be used with patients aged 18 or above who are undergoing CapE as part of the screening process for small bowel lesions. It should not be employed in pregnant women (for which capsule endoscopy procedure is not recommended) or children, as the algorithm was not trained on data from these demographics.

6. Performance characteristics of the device

Deep Capsule® AI model allows the detection and differentiation of endoscopic lesions. In a pilot clinical study Deep Capsule lesion detection rate was evaluated across 330 videos. The videos went through Standard of Care (SoC) and expert evaluation to establish a ground truth (Gold Standard). The evaluated lesions included xanthoma/lymphangiectasia (XL), ulcers/erosions (UE), vascular lesions (V), protruding lesions (PR), and blood (B). Deep Capsule had the following performance metrics:

Table 2: Classification metrics Sensitivity, Specificity, Precision, PPV, NPV and AUROC of Deep Capsule®

Lesion Type	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	Accuracy (95% CI)
Xanthoma/lymphangiectasia (XL)	**0.950*** (0.910 - 0.972)	0.576 (0.490 - 0.657)	0.771 (0.715 - 0.820)	**0.886*** (0.803 - 0.937)	**0.802*** (0.756 - 0.841)
Ulcers/Erosions (UE)	**0.931*** (0.875 - 0.963)	0.866 (0.812 - 0.906)	0.819 (0.749 - 0.872)	**0.951*** (0.910 - 0.974)	0.892 (0.854 - 0.921)
Vascular Lesions (V)	**0.964*** (0.931 - 0.982)	0.757 (0.668 - 0.828)	0.892 (0.847 - 0.925	**0.910*** (0.833 - 0.954)	**0.897** * (0.859 - 0.925)
Protruding Lesions (PR)	**0.959*** (0.863 - 0.989)	0.787 (0.736 - 0.831)	0.439 (0.349 - 0.534)	0.991 (0.968 - 0.998)	0.812 (0.766 - 0.851)
Blood (B)	0.969 (0.843 - 0.994)	0.997 (0.981 - 0.999)	0.969 (0.845 - 0.993)	0.997 (0.981 - 0.999)	0.994 (0.978 - 0.998)

* p-value for difference between AI-aided and SoC < 0.025

where:

- *Detection Rate:* The proportion of exams where at least one small bowel lesion is detected.
- *Sensitivity*: The proportion of true positive cases correctly identified by Deep Capsule®.
- *Specificity*: The proportion of true negative cases correctly identified by Deep Capsule®.
- *Precision*: The proportion of positive predictions that are true positives.
- *Positive Predictive Value (PPV):* The proportion of true positives among all positive test results.
- *Negative Predictive Value (NPV):* The proportion of true negatives among all negative test results.
- *Accuracy*: The overall proportion of correctly classified cases (true positives + true negatives) out of all cases.

7. Technical Specifications

To ensure the safe operation of the Deep Capsule® device, users must meet the following requirements:

1. Computer
    a. Platform
        i. PC: Windows 7 or later
        ii. Mac: macOS 10.10 or later
    b. Web Browser:

i. Recent versions of major browsers such as:
   1. Google Chrome (Chromium-based)
   2. Mozilla Firefox
   3. Microsoft Edge (Chromium-based)

ii. Ensure the browser is updated to the latest version to support all HTML5 features.

c. Hardware:
   i. Required: 4 GB of RAM
   ii. Required: 1 GHz CPU
      1. Recommended:
         a. Intel Core i5 12Gen
         b. AMD ryzen 5 5000 series
         c. Apple M1
   iii. Storage
      1. 200Gb

d. Screen Resolution:
   i. Minimum resolution of 1280x1024 pixels for proper display of content

2. Internet Connection:
   a. A stable connection with broadband speed.

In terms of compatibility, Deep Capsule® is designed to predict videos from the Jinshan OMOM® HD Capsule Endoscopy System, GIVEN PillCam™ family of devices (PillCam™ SB1, PillCam™ SB2, PillCam™ SB3), and ENDOCAPSULE 10 System medical devices. The Capsule Endoscopy Software (CapES), may be part of the Capsule Endoscopy (CapE) system or an individual medical device. Table 1 identifies the endoscopy capsules, the CapES, and the file origins and formats compatible with the Deep Capsule® .

Table 1: Compatibility Overview

Device	Capsule Endoscopy Software (CapES)	File Origin	File Format
PillCam™ SB1	PillCam™ Software v9	CapES Processed Video File	.MPG
PillCam™ SB1	PillCam™ Software v9	CapES Raw Data Video File	.avi
PillCam™ SB2	PillCam™ Software v9	CapES Processed Video File	.MPG
PillCam™ SB2	PillCam™ Software v9	CapES Raw Data Video File	.avi
PillCam™ SB3	PillCam™ Software v9	CapES Processed Video File	.MPG

PillCam™ SB3	PillCam™ Software v9	CapES Raw Data Video File	.gvf
ENDOCAPSULE 10 System	ENDOCAPSULE 10 V2	CapES Processed Video File	.mp4
ENDOCAPSULE 10 System	ENDOCAPSULE 10 V3	CapES Processed Video File	.wmv
OMOM® HD system	Omom Vue v7	CapES Processed Video File	.avi

Notes:

- **CapES Processed Video File:** Files created using the export method on the original Capsule Endoscopy Software (CapES). These files are specifically generated by the software's built-in export function, ensuring they are formatted and encoded according to the software's standards for compatibility and performance.
- **CapES Raw Data Video File:** Files that reside within the patient's raw data folder on the operating system where the CapES is installed. Unlike exported files, these do not need to be generated by the software's built-in export function. They reflect the data as it was originally captured and stored during the endoscopy procedure, without any additional modification or enhancement by the software.

Table 1 provides a clear overview of the compatible devices, software versions, and file formats that the Deep Capsule® can process, ensuring users can accurately and effectively use the platform.

8. Requirements for special facilities, or special training, or particular qualifications of the device user

There are no requirements for special facilities.

Deep Capsule is designed to be used by DHCs who must be properly trained in the use of Deep Capsule.

9. How to Use Deep Capsule

Login page

- ***Log in*** and ***Register*** buttons at the top right corner.

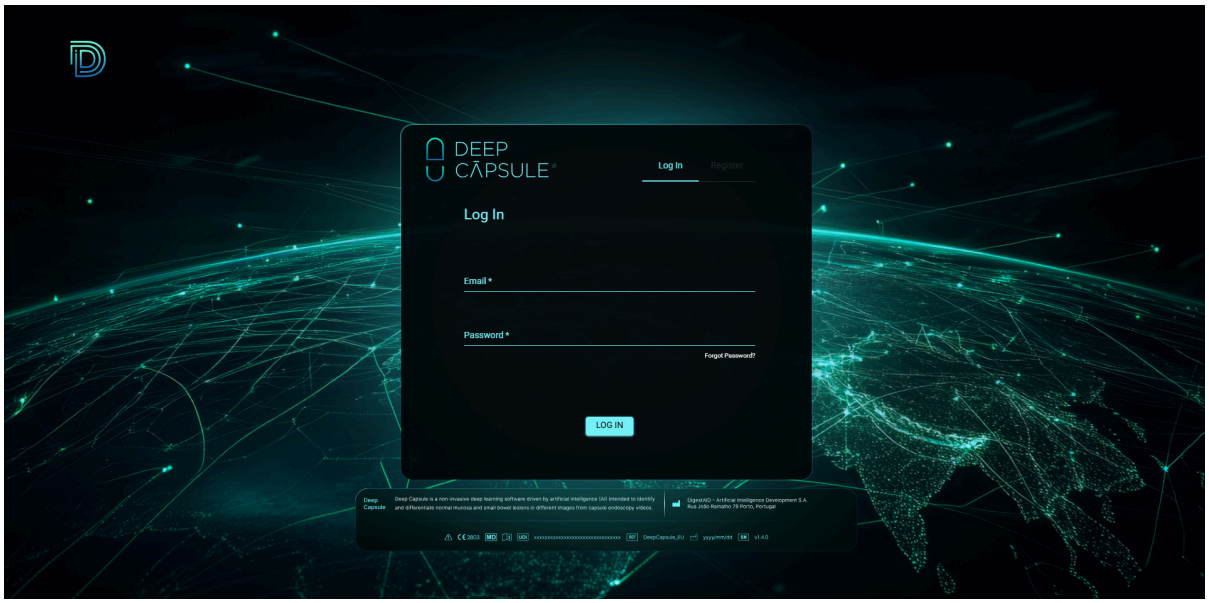


Fig. 1 - Login Page

NOTE: If you do not have login yet, you need to create a new account via the ***Register*** button at the top right corner. If your Institution is not registered yet, please contact our support team at support@digestaid.health.

Access pages

Register

- On the top, right click ***Register***;
- Enter your personal and professional information;
- Confirm the information and submit.



Fig. 2 - Register - Personal Information Step

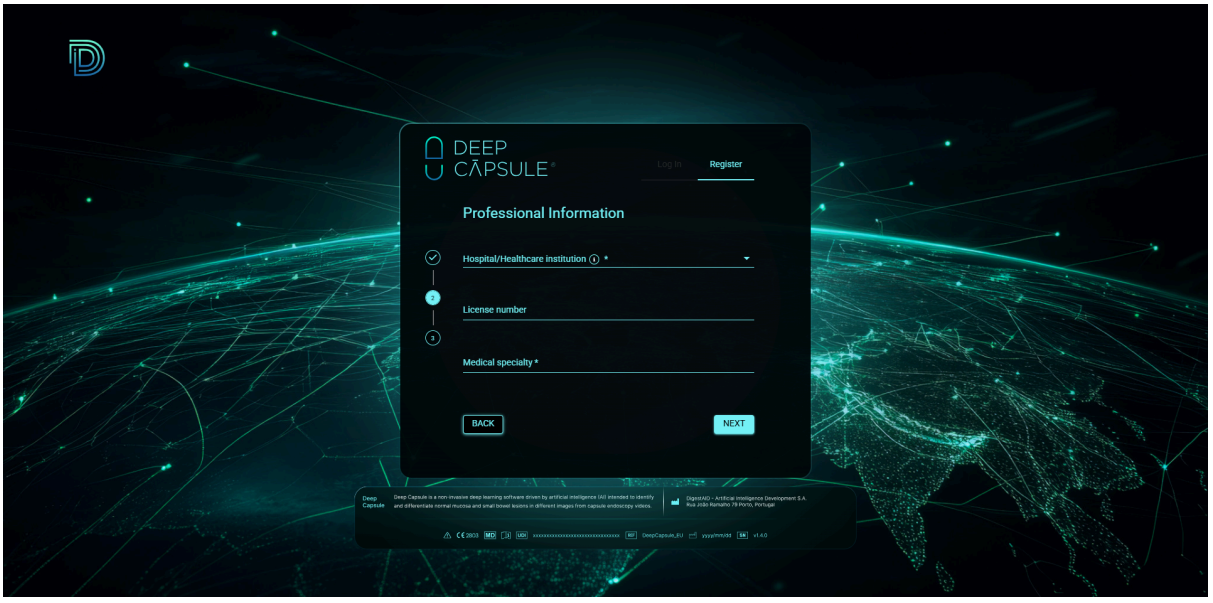


Fig. 3 - Register - Professional Information Step

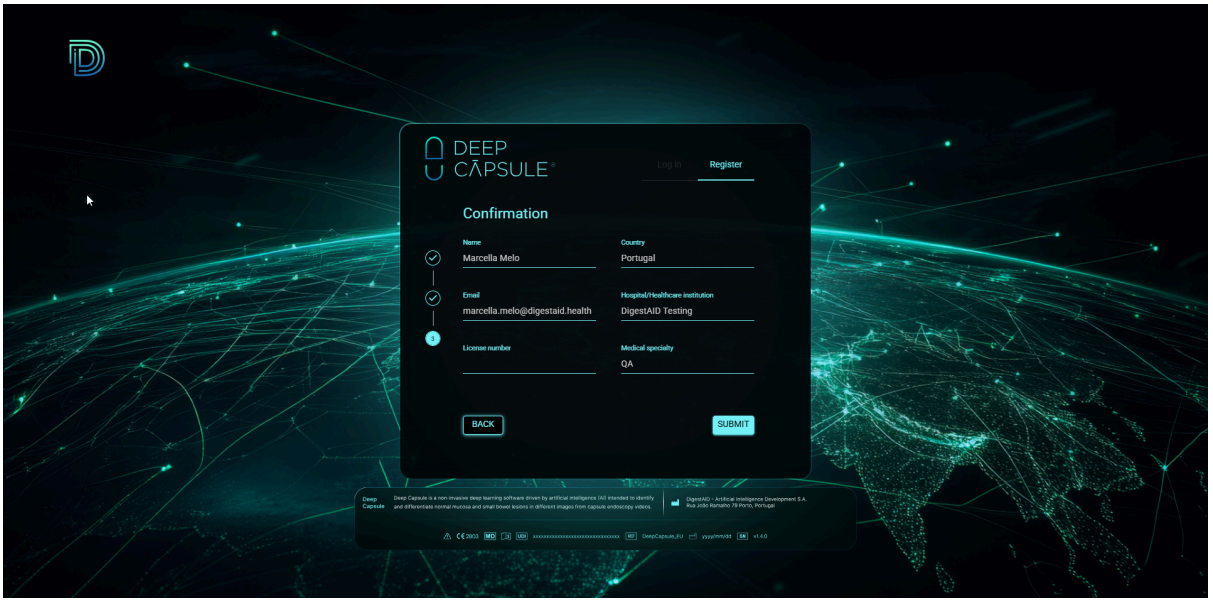


Fig. 4 - Register - Confirmation Step

Two-Factor Authentication (2FA)

After finishing the registration process, a verification email will be sent to the registered email address. After you log in with your credentials, an Account Setup page will appear, prompting you to verify your email and to configure a phone number to activate two-factor authentication (2FA).

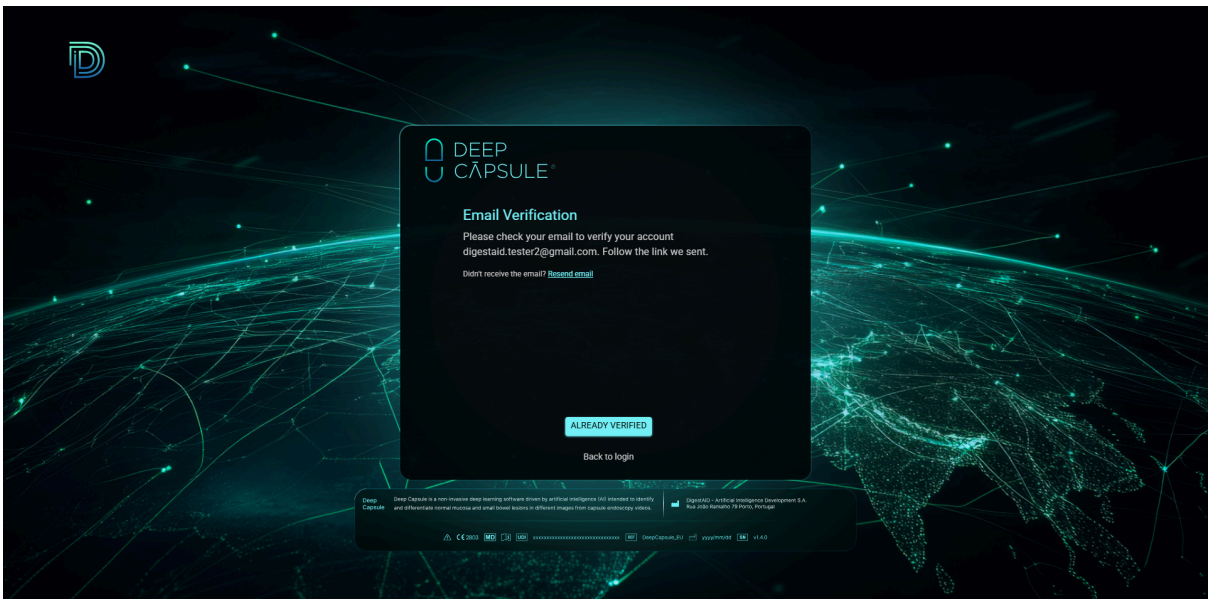


Fig. 5 - 2FA - Email Verification Tab

You can verify your email address by accessing the inbox of the email you registered with. You may open the verification email you received and click on the link provided.

- After verifying your email, select ***Already Verified***, and you'll navigate to the second step to enable two-factor authentication (2FA);
- You may choose the country calling code and insert your phone number in the input field provided;
- Lastly, click ***Submit,*** and you'll be redirected to the 2FA code verification page.

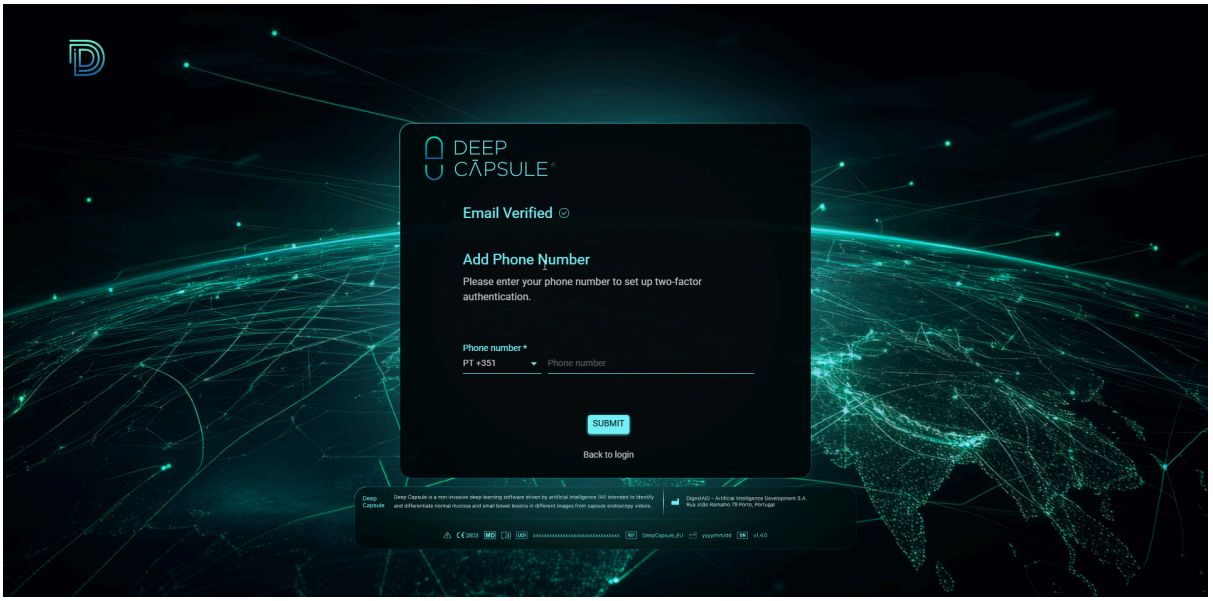


Fig. 6 - 2FA - Add Phone Number

After registering your phone number, a ***verification code*** will be sent to your phone via SMS.

- ***Enter the code*** in the respective fields;
- Once you submit the ***correct code***, your account will be secured with 2FA, and the Account Setup process will be complete;
- You will then be redirected to the **Dashboard page.**

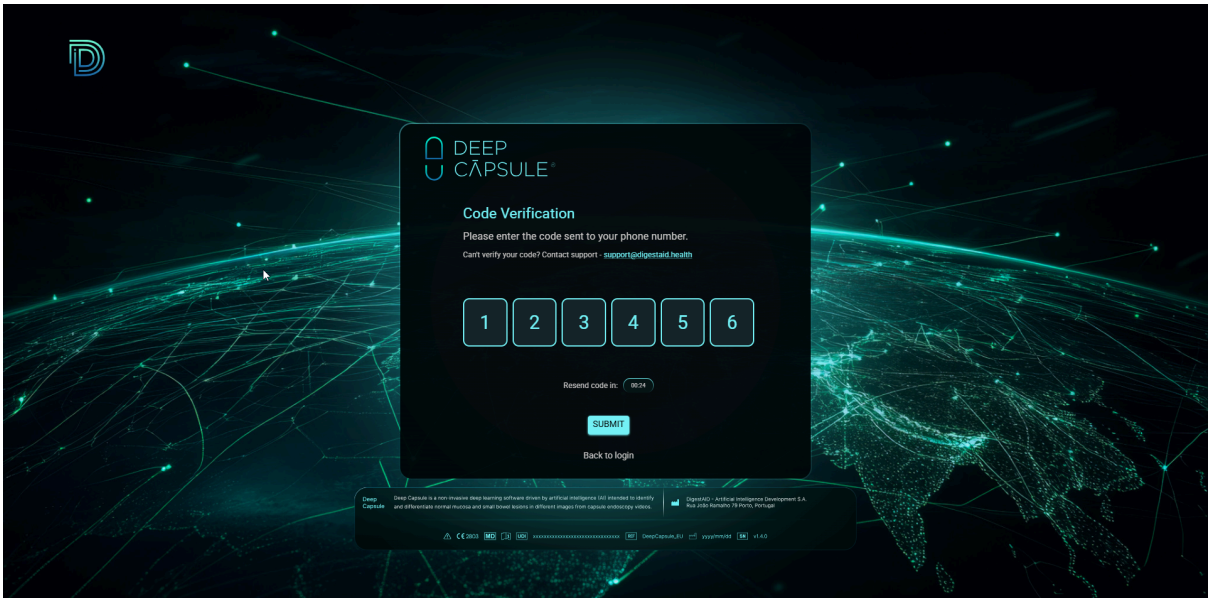


Fig. 7 - 2FA - Code Verification

- If the code is ***incorrect*** or not received, you can request a new one by clicking ***Resend code***.

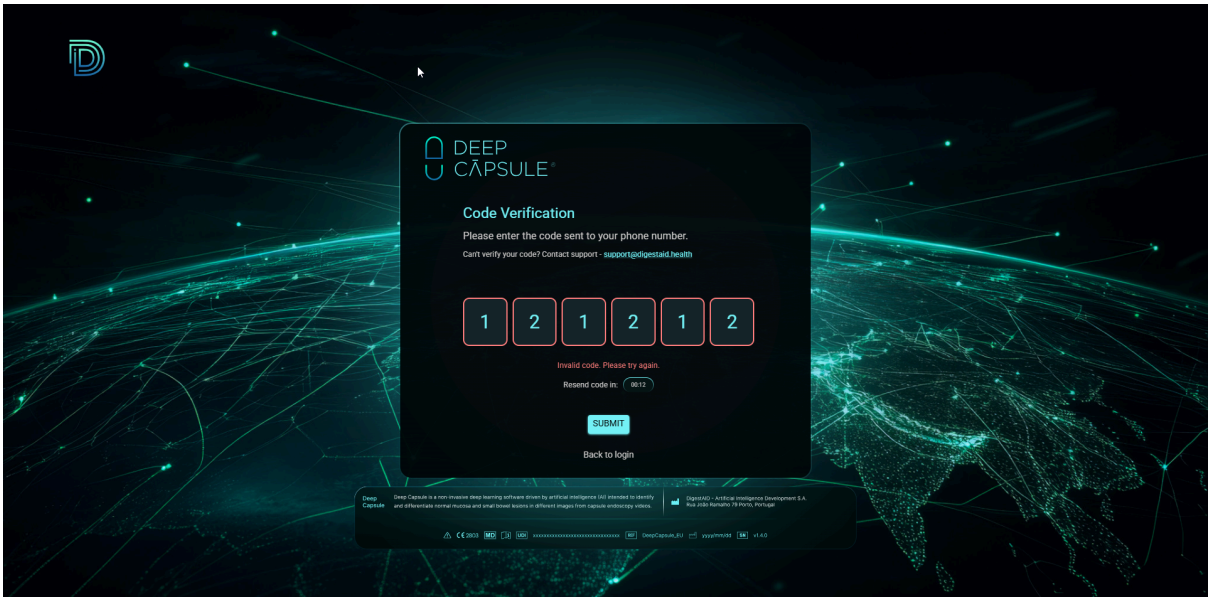


Fig. 8 - 2FA - Incorrect Code / Resend Code

- Once you submit the ***correct code***, your account will be secured with 2FA and the registration process will be complete.
- The user will be redirected to the **Login page**.

Log in

When you access the application, this is the first page that you will encounter.

- If you have clicked on the Register tab (on the top right corner), click ***Log in;***
- Insert your email address and password into the Login Form and click the ***LOG IN*** button in the bottom section.

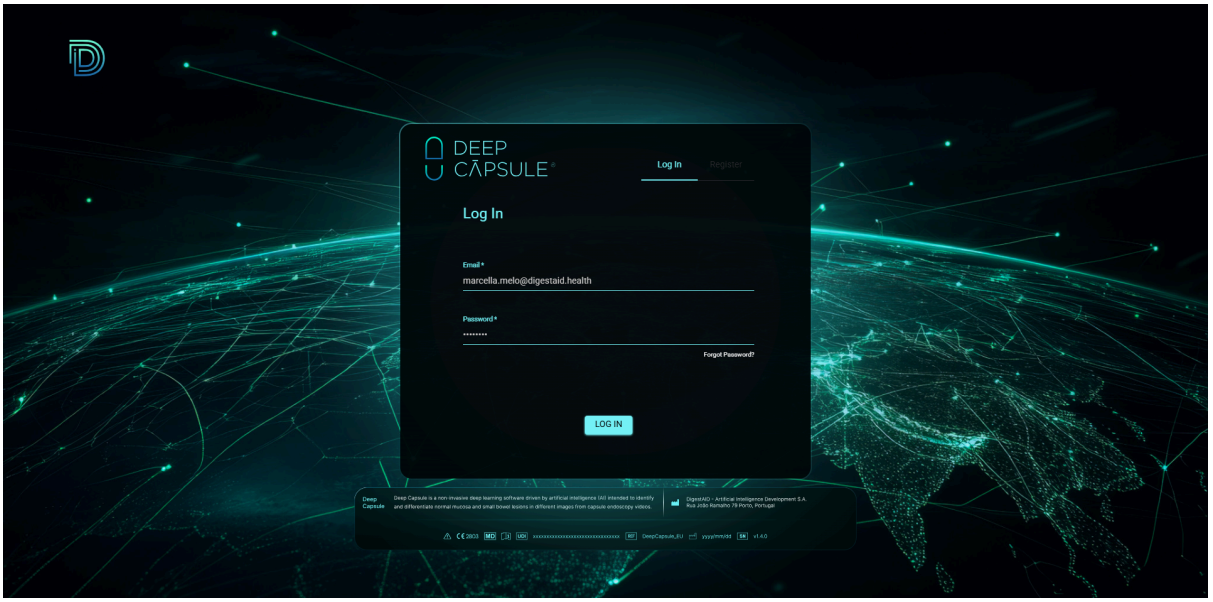


Fig. 9 - Login Form

NOTE: The application has a session timeout of 2 hours. If you need to sign out we advise you to do it directly using the ***Log Out*** button in the top right corner (user settings). Do not simply close the window. Otherwise, people with access to your workstation could continue to work within that session time using your login.

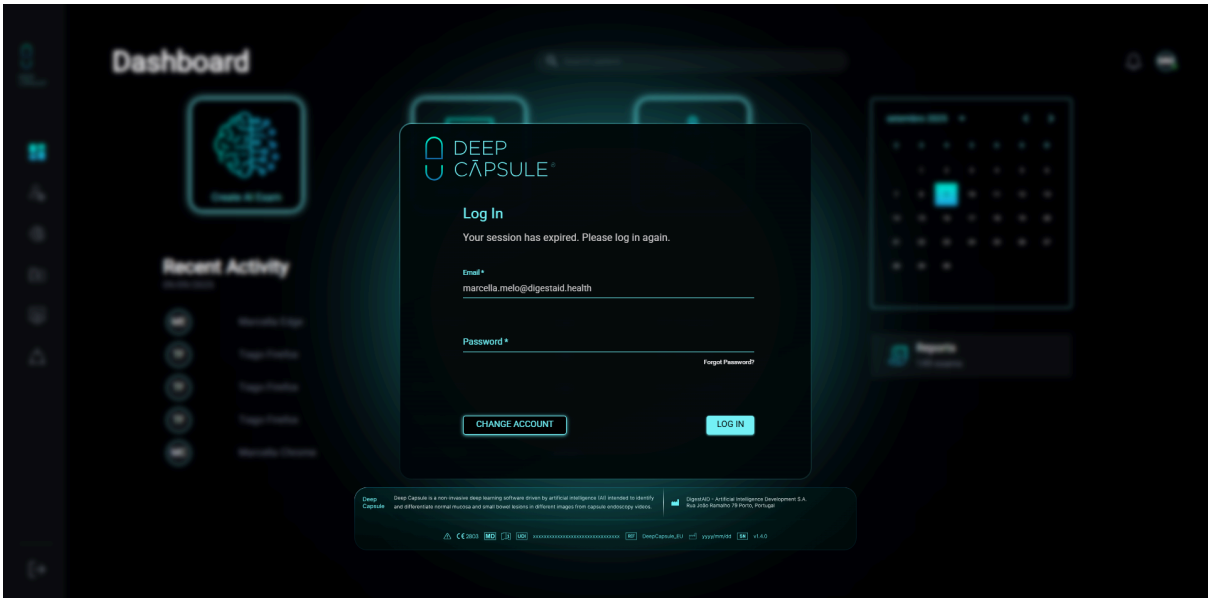


Fig. 10 - Session Expiration Pop-up Modal

Interface

The internal user interface includes the following sections:

1. *Navigation Selector;*
2. *Content Area;*
3. *User Settings and Notifications;*
4. *Search Bar.*



Fig. 11 - Interface

1. Navigation Selector
    - Use the Navigation Selector to access the different application panels.
2. Content Area
    - The contents of the selected panel will be displayed in this area;
    - Here, you can quickly and easily carry out actions related to the selected panel.
3. User Settings and Notifications
    - Use this area to access My Account page, access the About page or to log out;
    - Notifications regarding AI report availability will appear in the notifications section.
4. Search
    - You can search for a specific patient by simply typing keywords into the search bar and selecting the patient from the dropdown list;
    - You may search for the patient's first and last names, and also their identification number.

Panels

The available *panels* are displayed in the *Navigation Selector*. Once you select a *panel,* all related information will be displayed in the *Content Area*.

Dashboard

The *Dashboard* will help you access the details of the most recent examinations. Here, you also have a calendar for consultation and quick shortcuts to navigate to the main *panels*: *Create AI Exam*, *Study Manager,* and *Patient List.*

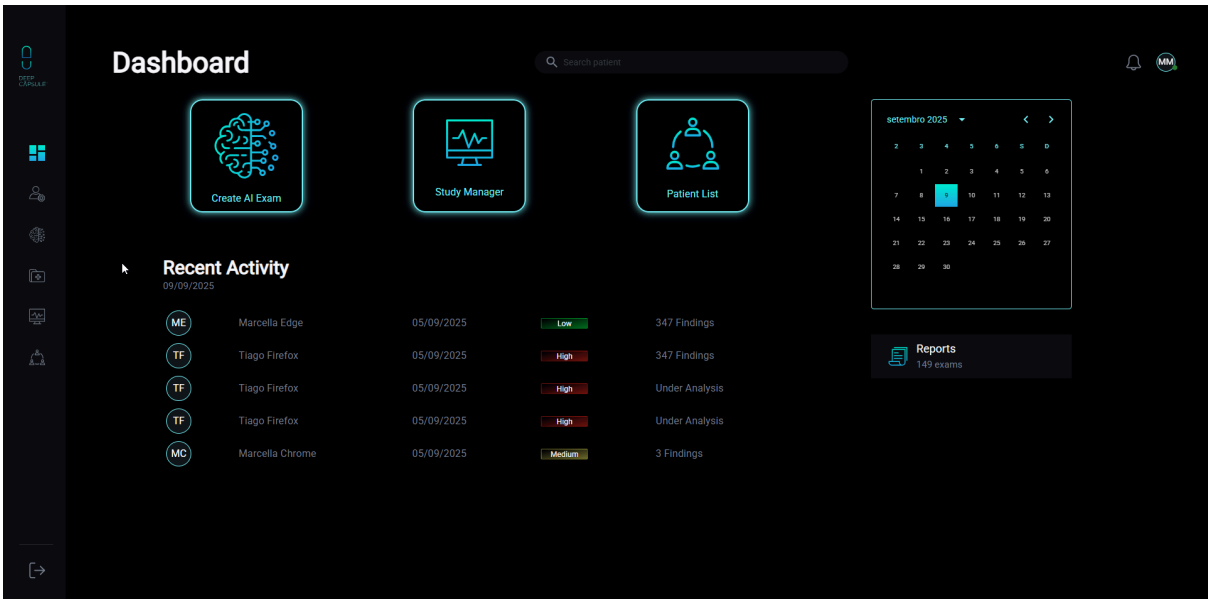


Fig. 12 - Dashboard

About

In this section, you can view the Release Notes, the Instructions for Use, and the End-user License Agreement by clicking on the following button: .

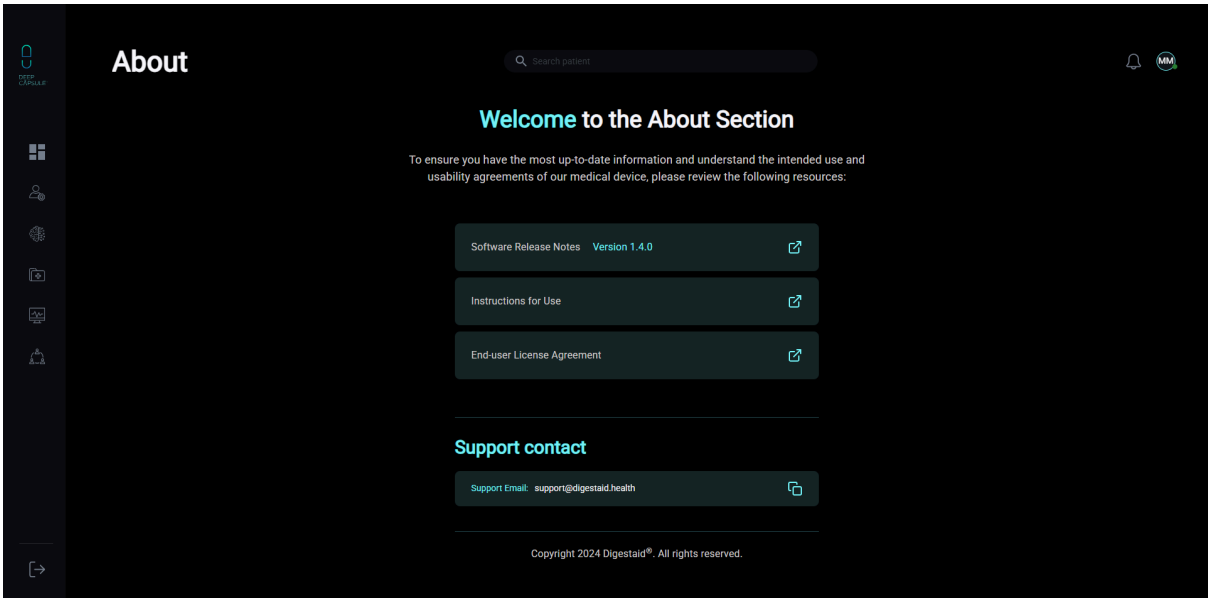


Fig. 13 - About

My Account

To update your profile information, go to ***My Account*** by clicking the corresponding *Selector* (left side navigation menu) (1) or, as explained above, by clicking on the user settings icon (top right corner section) (3). In this *panel,* you can see and manage all your details.

- **Read-Only Fields:** Hospital/Health Institution, Email, and Phone Number;
- **Editable Optional Fields:** Biography, Profile photo, and License number;
- **Editable Required Fields:** Medical specialty and Country;
- To **update your password,** click ***Send Password Reset Email***. An email with a reset link will be sent to your email account immediately. After clicking on this link, please insert the new password and click ***Save***. The new password will then be activated.

NOTE: If you need to update your email or phone number, please contact our support team at support@digestaid.health

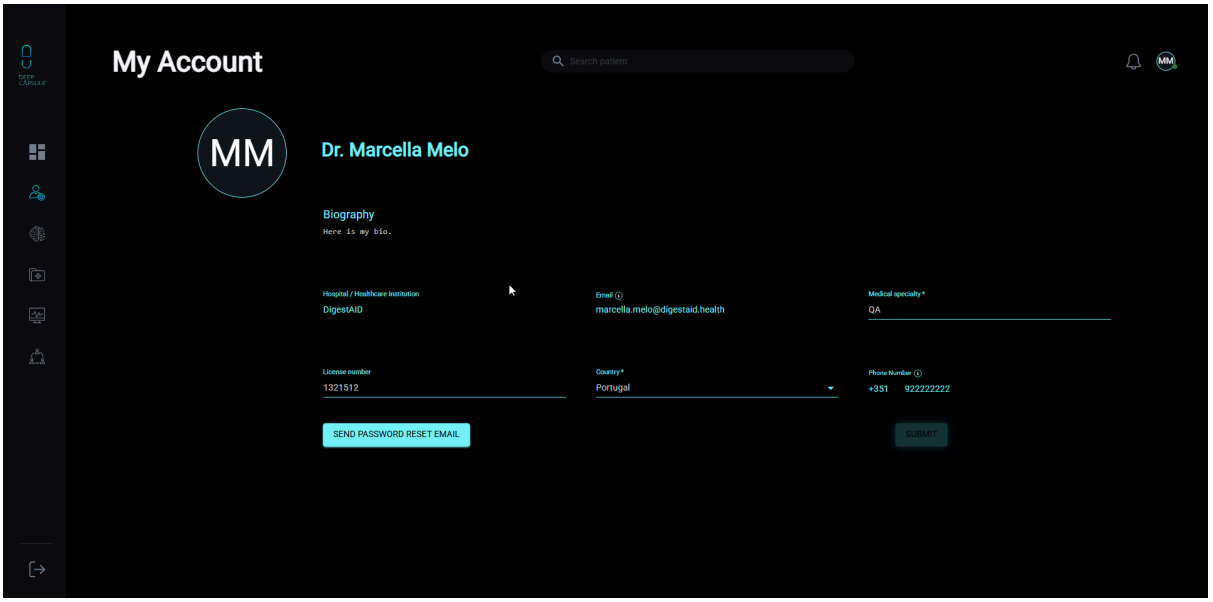


Fig. 14 - My Account

Create AI Exam

To create an AI Exam you need to:

- Search for a previously created patient in the Create *Patient* panel. You may filter your search by:
    - Health number, Passport number, Tax number, Social Security;
- After selecting the filter, type the number and click ***GO***.

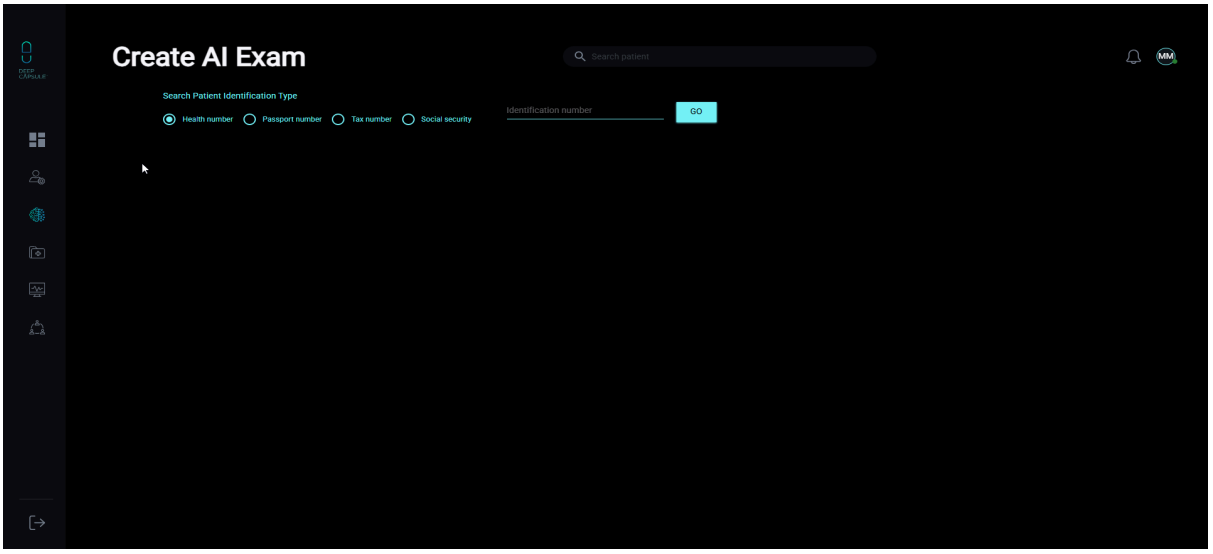


Fig. 15 - Create AI Exam - Search for Created Patient

- After this, you can select an existing draft exam or add a new one.

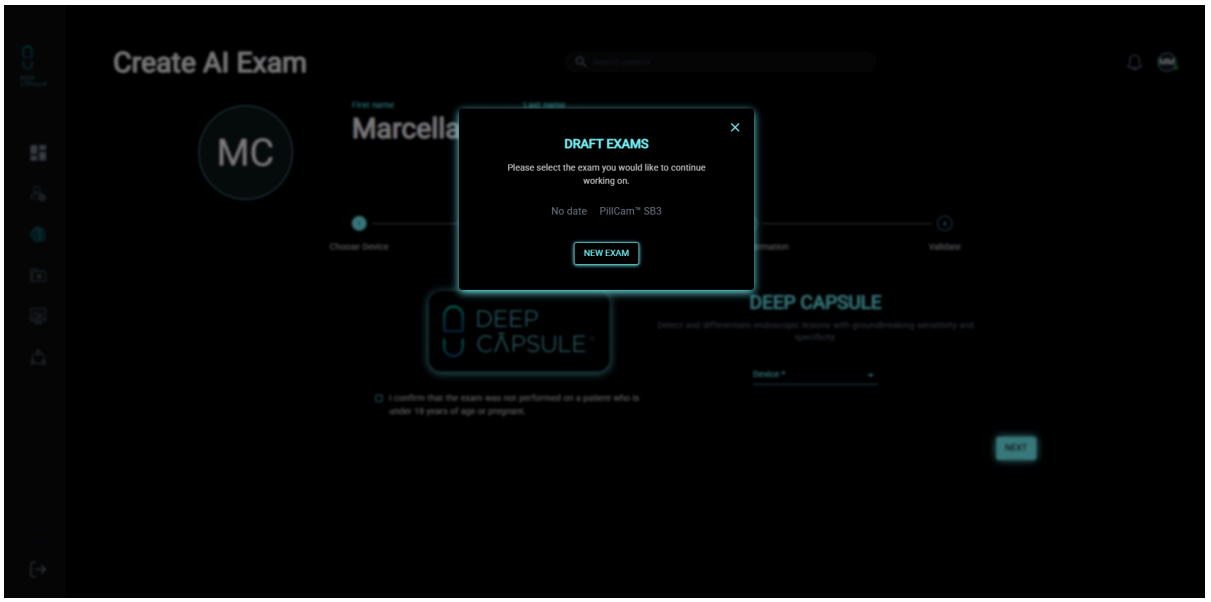


Fig. 16 - Create AI Exam - Draft Exams

- If you select an existing draft exam, you will resume the exam creation process, from the step in which the draft exam was saved.

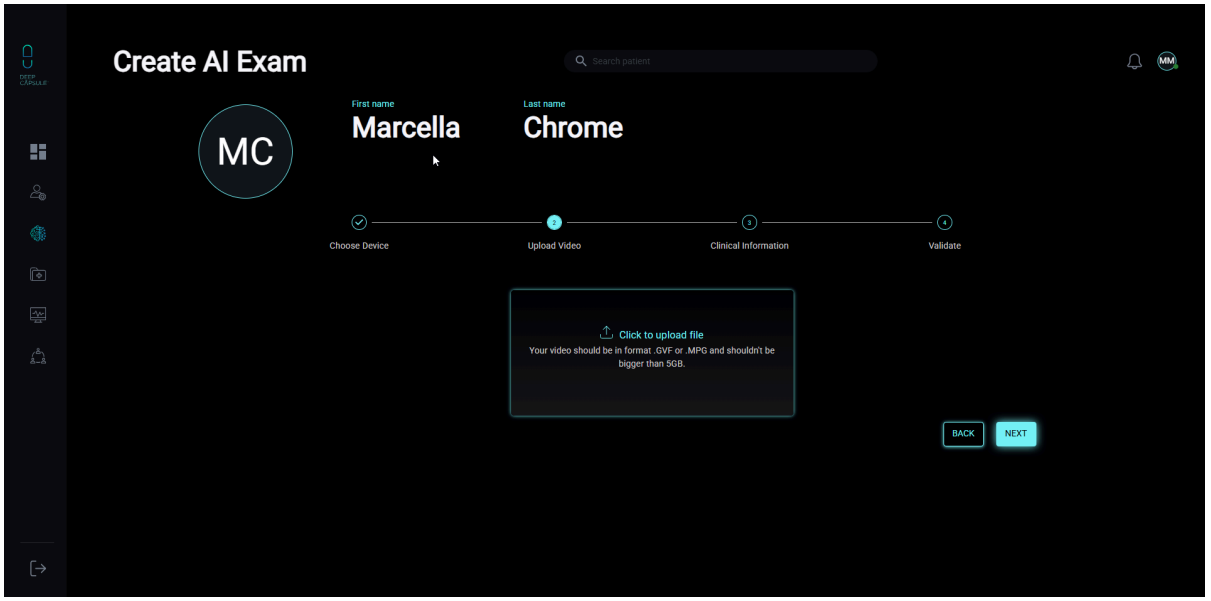


Fig. 17 - Create AI Exam - Resume Draft Exam

- If you select the ***New Exam*** button, you will need to:
    - Select the device, the capsule model that originated the CapE video;
    - Tick the ***checkbox*** to confirm that the target patient population disclaimer has been read and accepted;
    - Click ***Next*** to go to the Upload Video area.

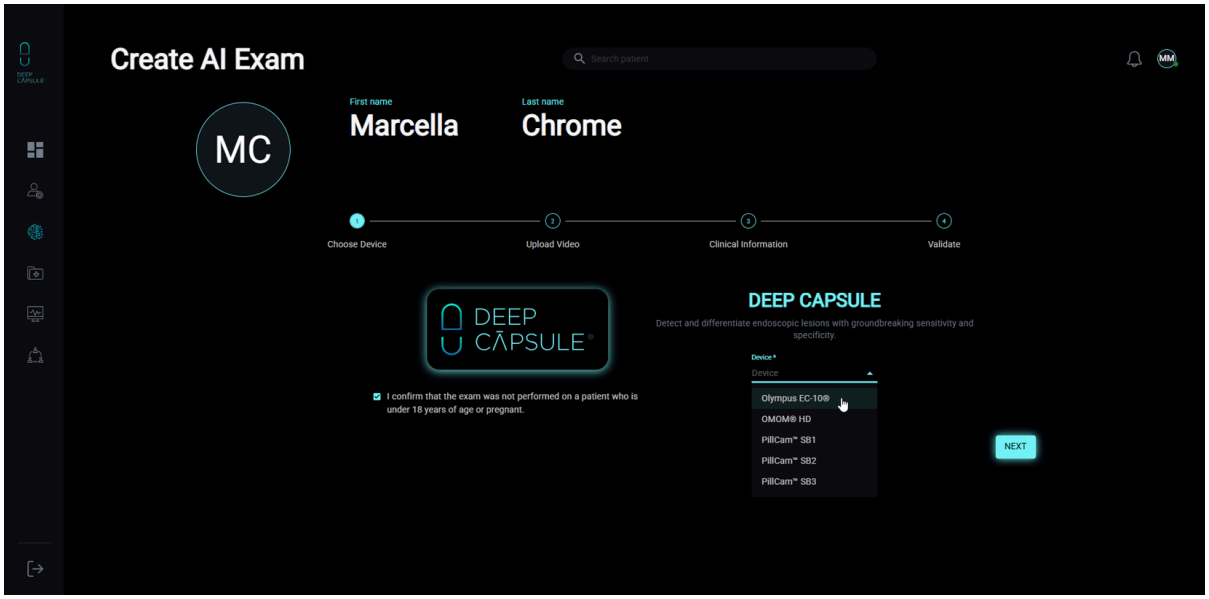


Fig. 18 - Create AI Exam - Choose Device - Device List

- You can now upload the video file by clicking on the area that says ***Click to upload file*** and selecting the file;
- After this, click ***Next*** button: a toast message will be displayed informing that the upload is in progress.

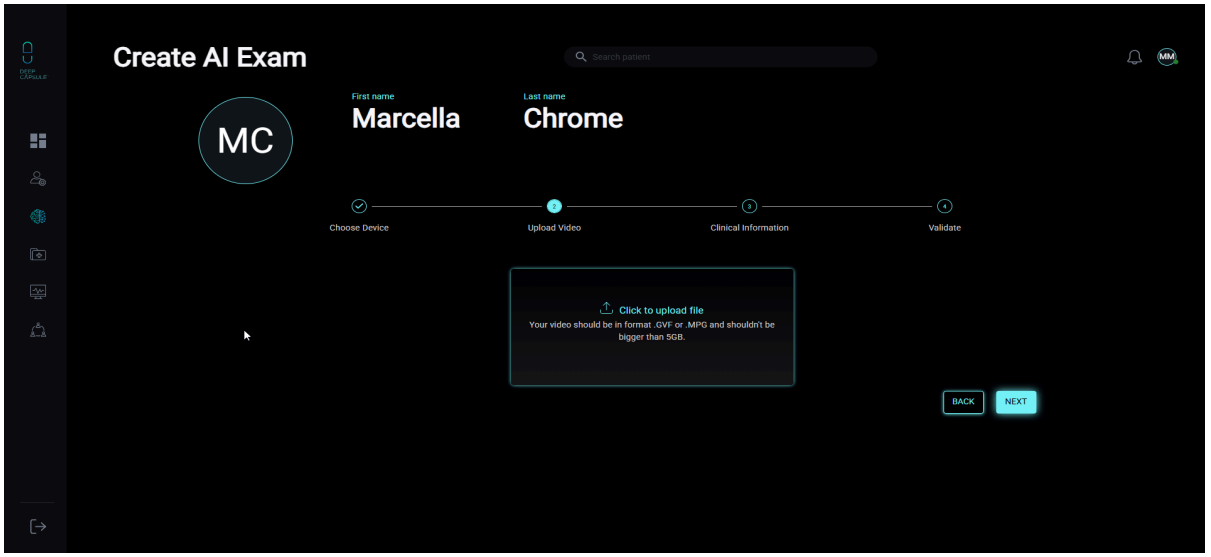


Fig. 19 - Create AI Exam - Upload Video

- Fill out the exam information:
  - Procedure date;
  - Exam collaborator (e.g.: DHC who did the prescription of the exam);
  - Exam priority - High, Medium, or Low (this priority is defined by the DHC according to the clinical indication, and exclusively as a patient management tool);
  - Clinical indication.

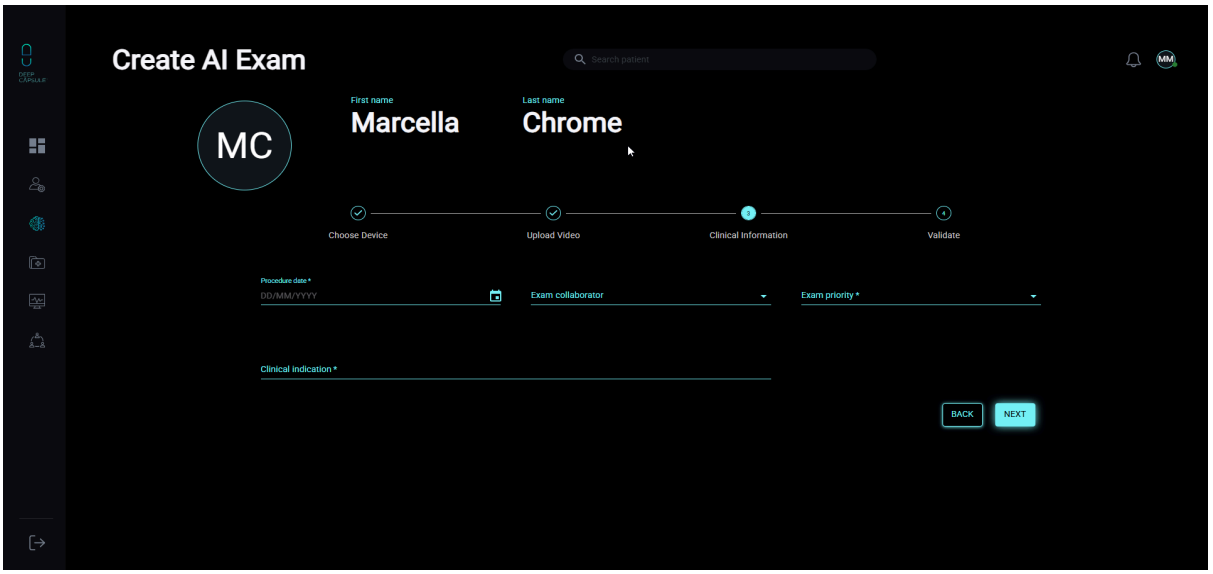


Fig. 20 - Create AI Exam - Exam Information

- Click ***Next*** to trigger the exam analysis.

NOTE: While the exam is being processed, the *panel* will show a loading animation. You may then navigate to other application panels. Once the exam results are ready, you will be able to validate the neural network analysis.

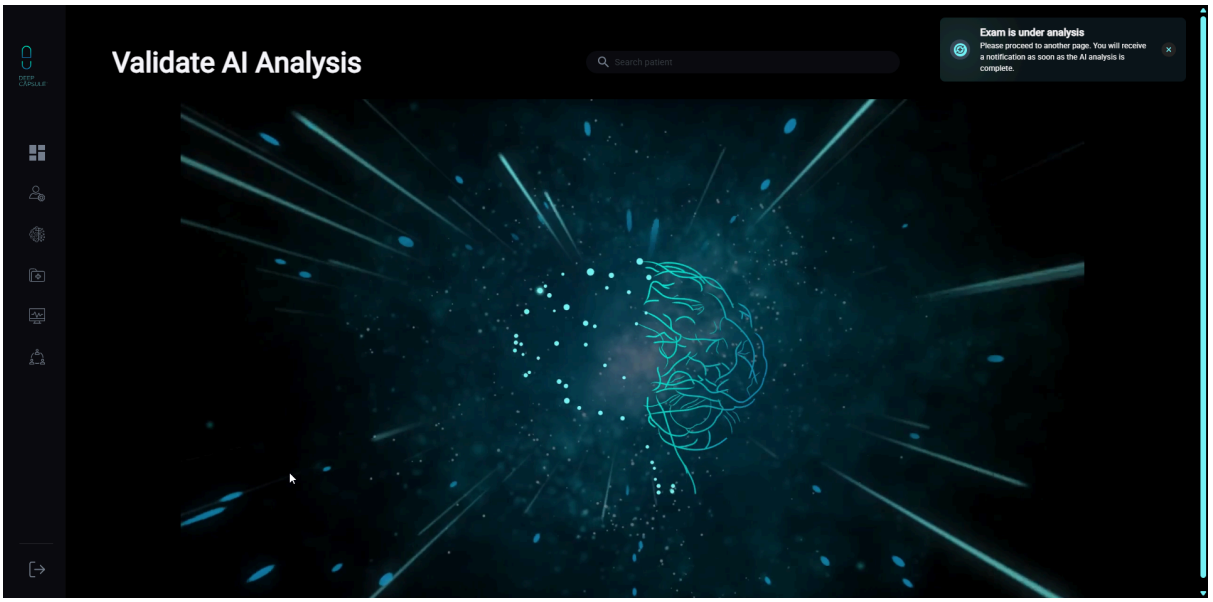


Fig. 21 - Validate AI Analysis - Loading Animation

Validate AI Analysis

- When the exam results are ready, you will view all the Predictions findings.

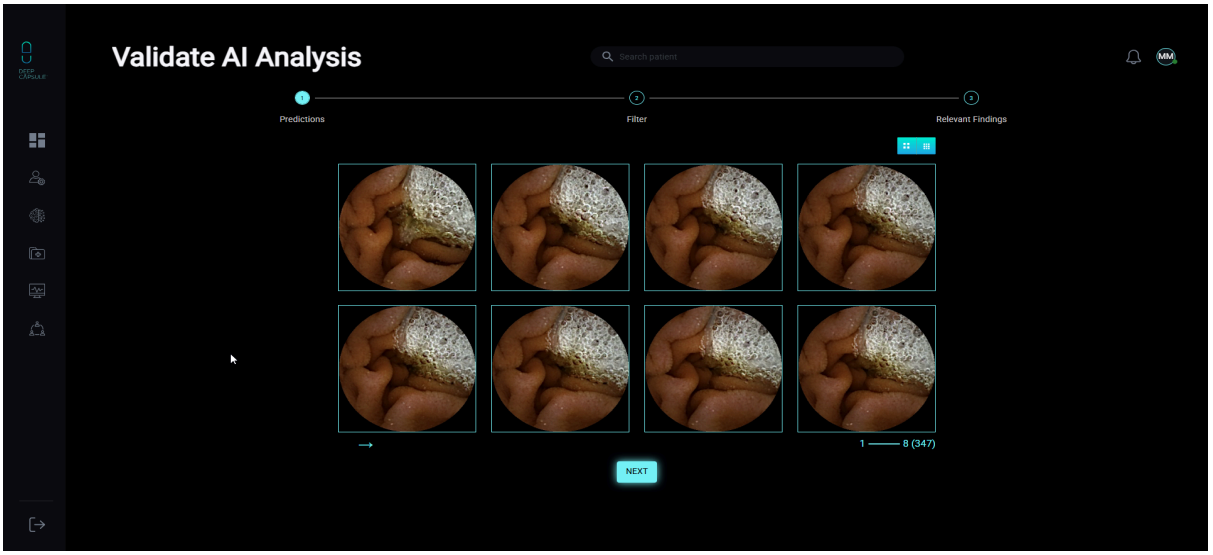


Fig. 22 - Validate AI Analysis - Predictions

- After this, click ***Next*** to be able to select the type of lesions you want to analyse.

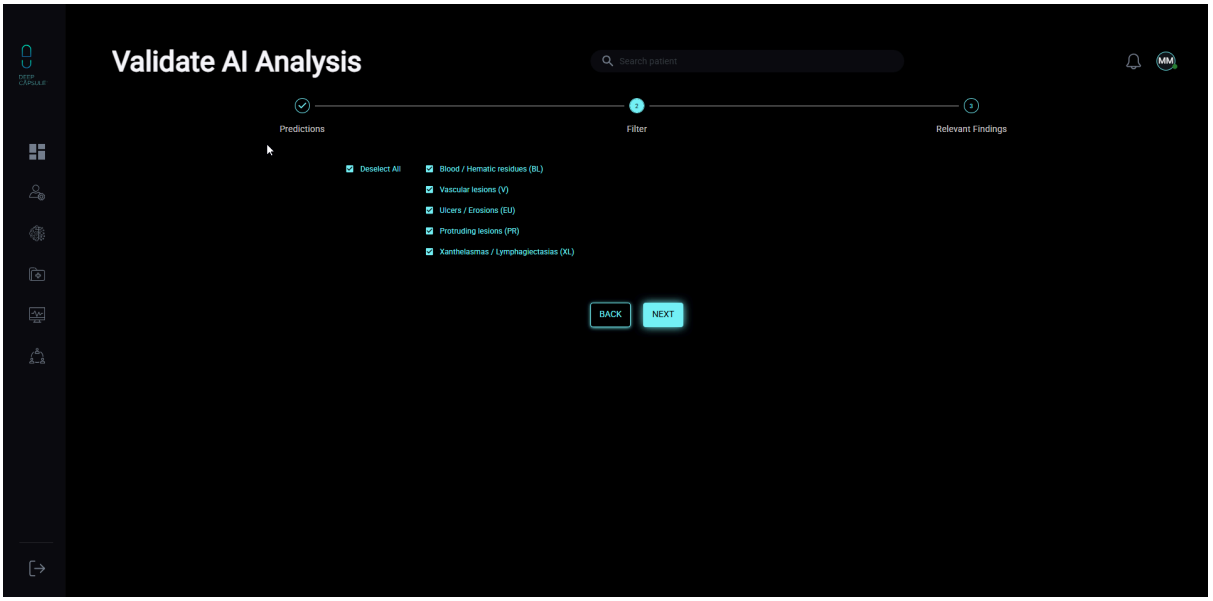


Fig. 23 - Validate AI Analysis - Filters

- After selecting the filter(s), click ***Next*** to see all the relevant findings.
- If you identify a lesion that has an incorrect lesion labelled, you can click the specific image, click the ***Reclassify Lesion*** button, and reclassify it according to your criteria. To save the image reclassification, you need to click the ***Save*** button, and also finish the exam validation.

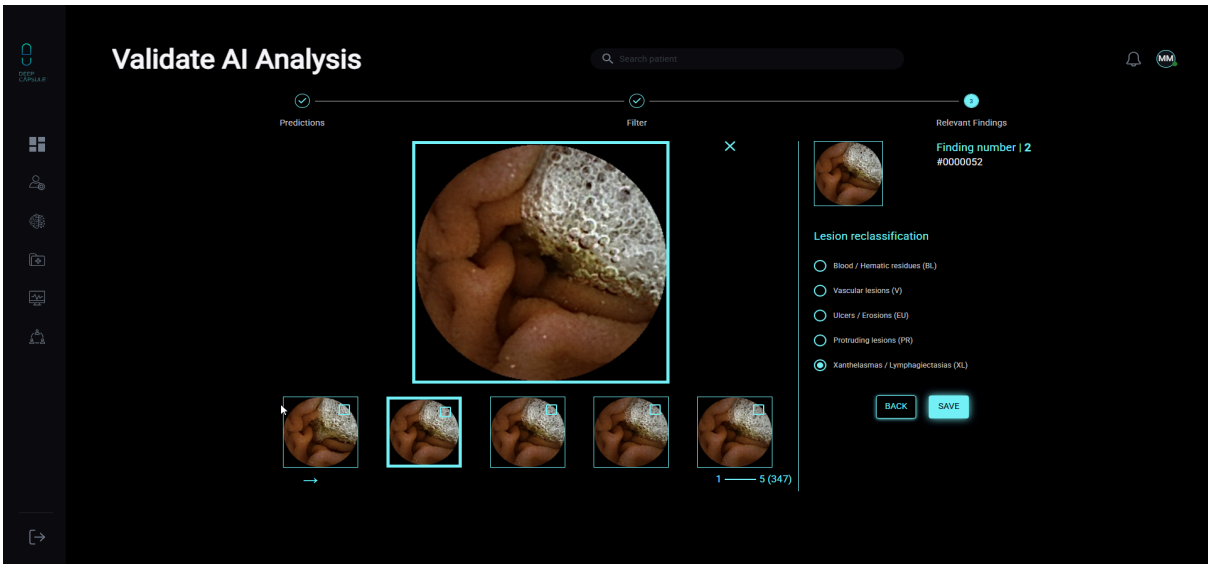


Fig. 24 - Validate AI Analysis - Image Reclassification

- You can select which findings you want to appear on the report and then click ***Save***.

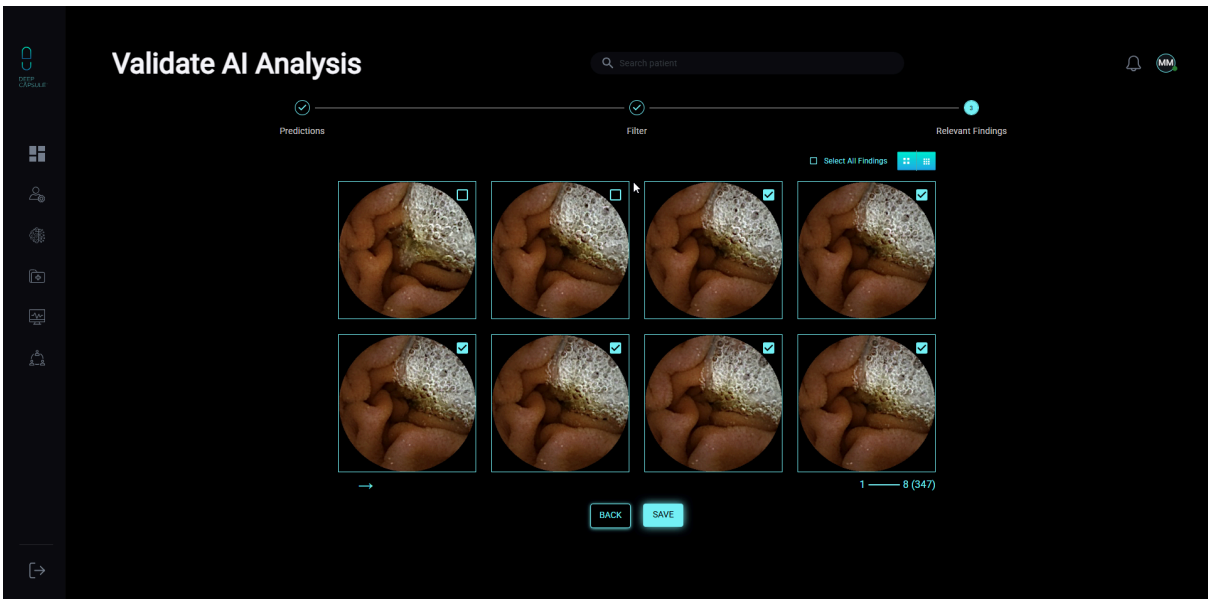


Fig. 25 - Validate AI Analysis - Relevant Findings

- After saving, you will see the Exam AI Report. For more information about this, please see the Patient List section.



Fig. 26 - Validation Saved - AI Report

Create Patient

You can access the *Create Patient* panel in two different ways: via *Create AI Exam* panel or via the *Navigation Selector* (1) displayed on the left side of the application.

- When creating a new exam (inside the *Create AI Exam* panel), if the patient is not found, a pop-up modal will be triggered with an option to create a new patient.

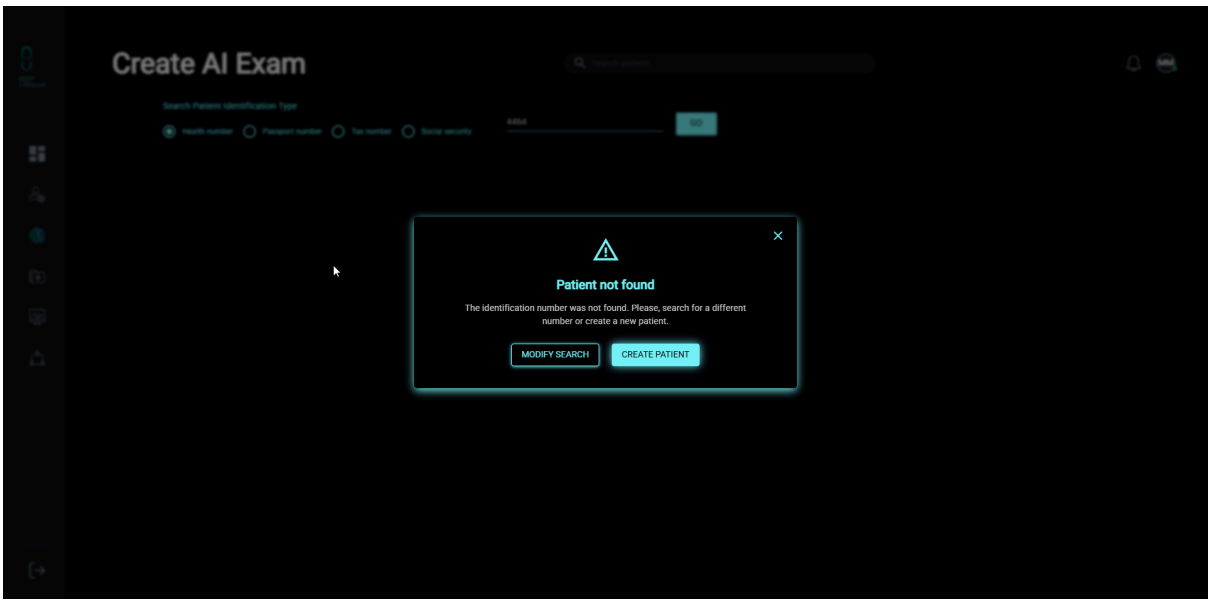


Fig. 27 - Create AI Exam - Patient Not Found Pop-up Modal

- After clicking on the ***Create Patient*** option, you will be redirected to the *Create Patient* panel.
- As explained above, you may also access this panel directly via the *Navigation Selector* (1), on the left side of the application, choose the *Create Patient* option.

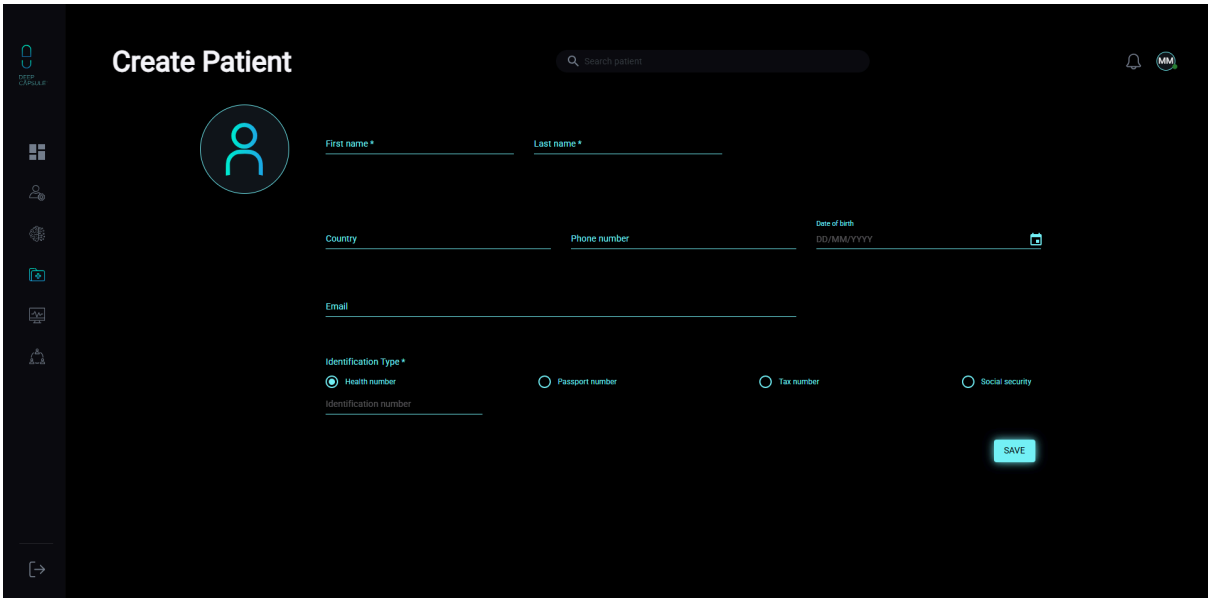


Fig. 28 - Create Patient Panel

- Here, you can create a patient by filling in all the required fields. You will need to insert:
  - *Header*: First name, Last name;
  - Patient details:
    - Required field: Identification Number;
    - Optional fields: Country, Phone number, Date of birth, Email.
- Click ***Save*** to create the patient.
- Once the patient is successfully created, you will be automatically redirected to the *Create AI Exam* panel. Then, you just need to follow the steps described above in the Create AI Exam section.

Study Manager

This is an area where the exam results are customized to you. In this panel, you can see an overall view of the exams created by you, filter the exam list and click on the row corresponding to the exam you wish to see.

- You may filter the results according to the patient's name and/or the procedure's date
- When you click on an exam row, you will navigate directly to its AI Report section.

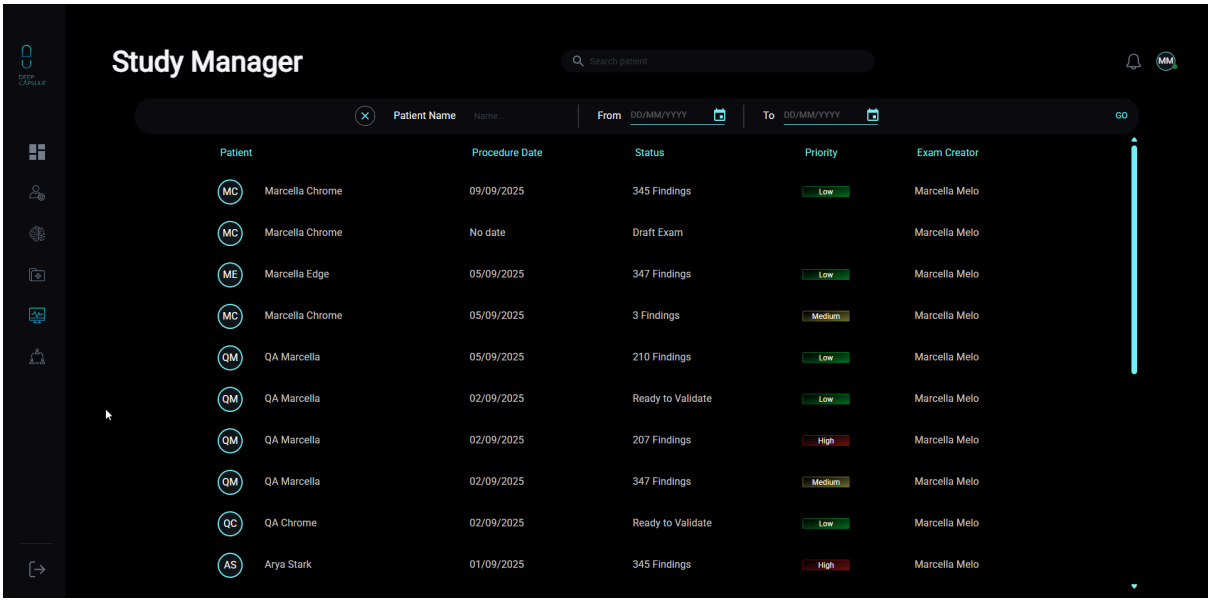


Fig. 29 - Study Manager Panel

Patient List

This panel shows a list of all the patients registered in your institution - or registered by you - according to the Data Agreement of your institution.

- A list of patients will appear on the left side, which you can sort alphabetically or by the update date.
- When you scroll down the list, more patients will be loaded, if available.
- You can click on the patient names to go to their *Personal Information*.

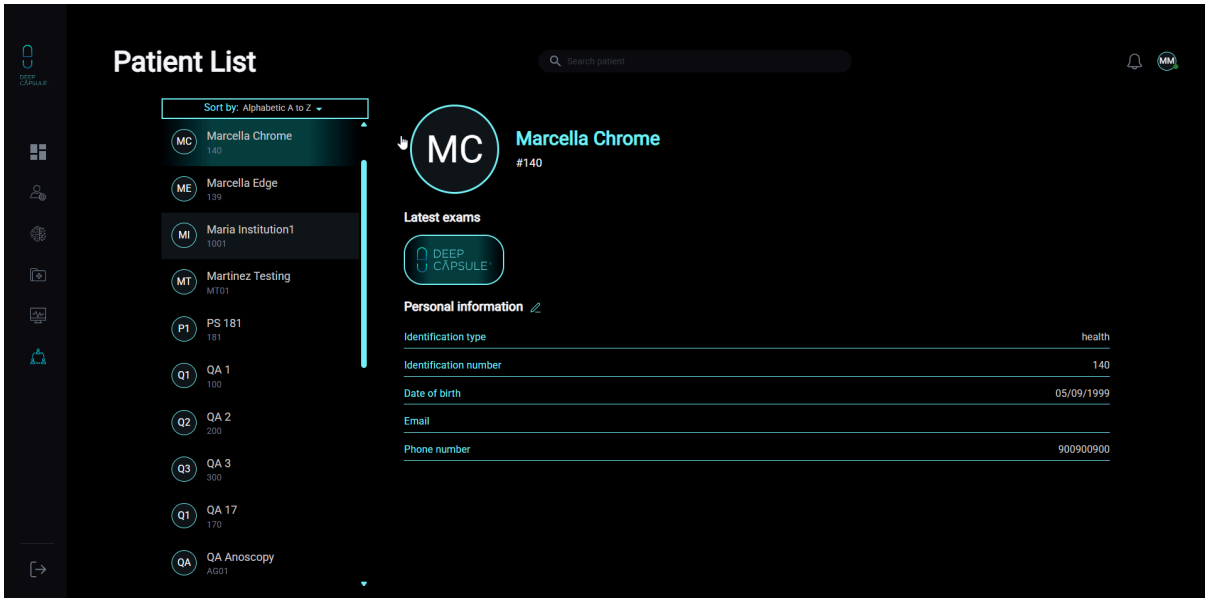


Fig. 30 - Patient List - Personal Information

- You can select the ***Deep Capsule*** button to see all exams associated with the selected patient.

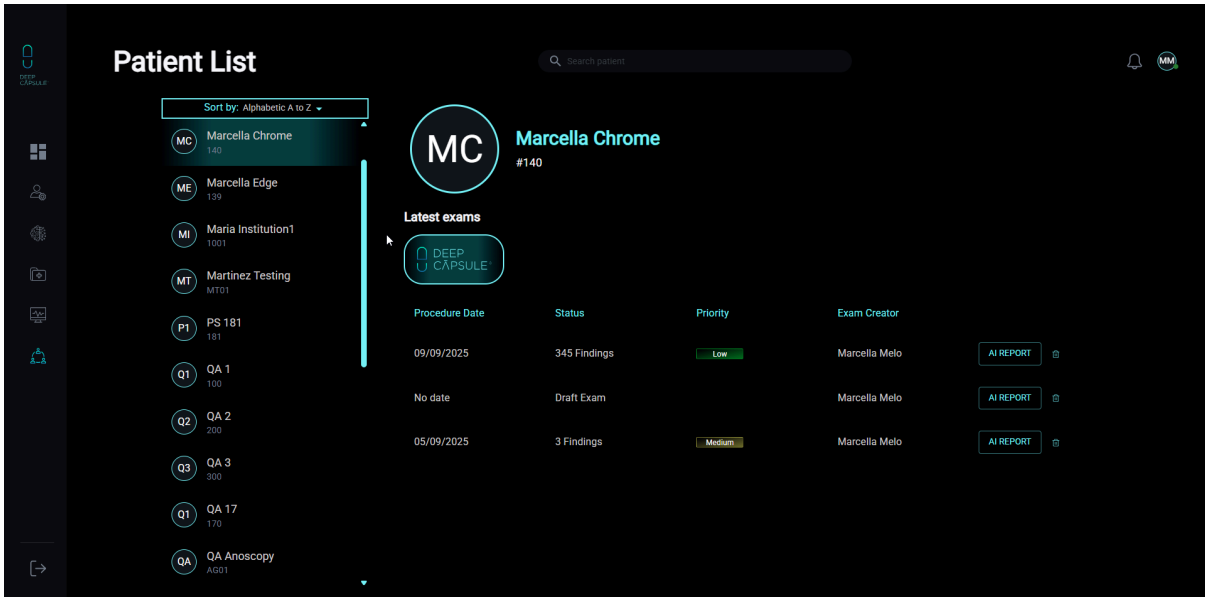


Fig. 31 - Patient List - Latest Exams

- You can access an exam and its details by clicking the ***AI Report*** button.
- The AI Report has:

- the video on the left side;
- A gallery of the AI reported findings with annotation options on the right. You can sort this gallery by “Frame Number”, “Certainty” or “Lesion Type”.

NOTE: Certainty is the numerical output of the model, represented as a list of percentage values, with one value for each type of lesion. Findings are determined from all images where the majority target (the type of lesion with the highest value in the list) has a value that exceeds the cutoff value (80% in the case of the Deep Capsule). Sorting by certainty means ordering by the values of each frame.

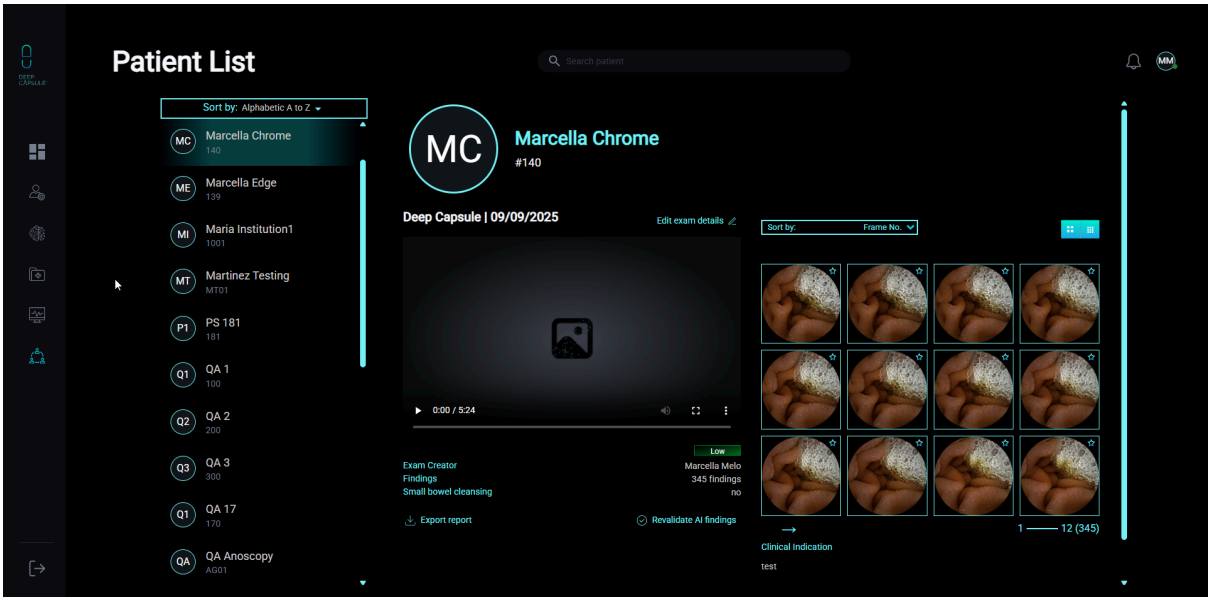


Fig. 32 - Patient List - AI Report

- In this panel, you can:
  - Review exam details - Procedure Date; Exam Collaborator; Exam Priority and Clinical Indication;
    - These can be edited in the ***Edit exam details*** button - After editing, click on ***Save*** button;
  - Review the number of findings in the exam;
  - Export the findings by clicking ***Export report.*** A PDF file will be exported to your workstation;
  - Revalidate AI findings: This option will re-run the Validate AI Analysis stage for a previously validated exam (see Validate AI Analysis);
  - Add a medical note by clicking the ***plus*** button in the Medical Notes area.

10. Warnings and Precautions

- Deep Capsule® is intended to be used as an adjunct to CapE and is not intended to replace expert DHC assessment. In particular:
    - The device does not perform any diagnosis.
    - The device is not intended to replace clinical decision-making.
    - The device is intended to provide adjunctive information to the DHC who performs CapE with an expected high level of clinical expertise.
- All users must be trained before using the device.
- Please read this IFU carefully and keep it for future reference.
- Internet connection loss may result in data loss.
- Incorrect patient registration or data upload may lead to inaccurate results.
- Credentials are unique and private. They should not be shared with any third party to prevent any privacy breach of the data.
- To protect unauthorised access, the user must log out after use. Also, the platform automatically logs the user out after 2 hours.
- It is advised to have an anti-malware software and the use of a firewall.
- The user is responsible for the directory where the downloaded reports are set, as it could cause a security problem.
- All exams with poor image quality caused by fecal matter or inadequate cleanliness should be discarded as they may affect the accuracy of Deep Capsule® findings.

11. Support

The helpdesk service provided to users of the system is available at the following contact:

E-mail: support@digestaid.health

Note: In the event that a serious incident has occurred related to device use, immediately report the event to the manufacturer, competent authorities, and any other regulators as required.

12. Revisions History

Version	Change description	Prepared by	Approval	
			Approved by	Date
1.0	First edition.	Tiago Figueiredo (Lead QA Engineer) and Marcella Mello (Senior QA Engineer)	Hélder Cardoso (Chief Medical Officer)	31/07/2024
1.1	Inclusion of new warnings, performance data update, and legal address update	Tiago Figueiredo (Lead QA Engineer) and Marcella Mello (Senior QA Engineer)	Hélder Cardoso (Chief Medical Officer)	05/03/2025
1.2	Inclusion of the two-factor authentication instructions.	Tiago Figueiredo (Lead QA Engineer) and Marcella Mello (Senior QA Engineer)	Hélder Cardoso (Chief Medical Officer)	24/07/2025

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