

Abstract

These are the instructions for the use of Sim&Predict™ version 2.0.0 medical device software to automatically process and analyze CTA and TOF MRA medical images of the head to provide the probability of the presence of unruptured saccular aneurysms in the medical image analyzed.

Contact information

For any request, technical assistance, or suspicion of a cybersecurity event, please contact support:

www.sim-and-cure.com
email: contact@sim-and-cure.com
phone: +33 (0)9 53 43 88 09

Any deficiencies that have occurred in relation to the device, that led, might have led or might lead to the death of a patient, user or other person or the temporary or permanent serious deterioration of a patient's, user's or other person's state of health must be reported to Sim&Cure and the competent authority in which the user and/or patient is established.

Under US FDA Regulation – Caution: Federal law restricts this device to sale by or on the order of a physician or other licensed practitioner.

Contents

1.	Symbols and abbreviations	4
2.	Product Information	5
2.1.	Intended Use	5
2.2.	Intended User	5
2.3.	Indications for use	5
2.4.	Intended patient population and medical conditions	6
2.5.	Contraindications	6
2.6.	Precautions for use	6
2.7.	Safety Warnings	7
2.8.	Adverse effects and residual risks	7
2.9.	Clinical performances	7
2.10.	Clinical benefits	8
3.	Product Description	8
3.1.	Mode of Action	8
4.	Installation & Network Security	9
4.1.	Installation	9
4.2.	IT-Network	9
5.	User System Requirements	9
5.1.	Supported operating systems	9
5.2.	Minimum hardware requirements	9
5.3.	Recommended hardware requirements	10
6.	Instructions for Use	10
6.1.	Start-up procedure	10
6.2.	DICOM Management	10
6.3.	DICOM Series Processing and Report Generation	11
6.4.	Probability color map	16
7.	Removal procedure	16
7.1.	Uninstallation	16
7.2.	Decommissioning	16
8.	Cybersecurity	17

8.1. Anomalous conditions announce 17

8.2. Log files 17

8.3. Configuration restoration by an authenticated privileged user 17

8.4. End of support..... 18

8.5. Malware detection..... 18

8.6. Antivirus 18

8.7. Private data..... 18

9. Software updates 19

1. Symbols and abbreviations

Depending on your territory, some symbols may be present in the labeling:

-  : indicates there is an obligation to read the instructions for use before using Sim&Predict software
-  : indicates the need to consult the electronic instructions for use
-  : indicates that caution is necessary when operating the device or that the current situation needs user awareness or action to avoid undesirable consequences
-  : indicates information intended to help the user take the right steps to operate the software correctly
-  0459: CE mark
-  : indicates the item is a medical device
-  : indicates a carrier that contains the Unique Device Identifier information
-  : indicates the version number of the software
-  : indicates the Sim&Predict software manufacturer, address, and date of manufacture.

Moreover, the instructions for use include the following abbreviations:

ACA	Anterior Cerebral Artery
AET	Application Entity Title
CPU	Central Processing Unit
CTA	Computed Tomography Angiography
DICOM	Digital Imaging and Communication in Medicine
FP	False Positive
ICA	Internal Carotid Artery
MCA	Middle Cerebral Artery
MPR	Multi Planar Reconstruction

MRA	Magnetic Resonance Angiography
PACS	Picture Archiving and Communication System
PCA	Posterior Cerebral Artery
SOP	Service Object Repair
TOF	Time of Flight
TSA	Trunk and Supra-Aortic Arteries
UID	Unique Identifier

2. Product Information

2.1. Intended Use

Sim&Predict is intended to automatically process and analyze CTA and TOF MRA medical images of the head to provide the probability of the presence of one or more unruptured saccular aneurysms in the analyzed medical images. The medical device software is intended to assist radiologists in the review and interpretation of medical images by providing additional information to support the detection of aneurysms. The software is intended to be used after the standard of care image interpretation and is not intended to replace the radiologist's clinical judgment or to provide a diagnosis. The device does not alter the original medical images.

2.2. Intended User

The intended users are radiologists. Users must be healthy and have all their intellectual abilities.

2.3. Indications for use

Sim&Predict is intended to automatically process and analyze CTA and TOF MRA medical images of the head of adult patients to provide the probability of the presence of one or more unruptured saccular aneurysms in the analyzed medical images. The medical device software is intended to assist radiologists in the review and interpretation of these medical images by providing information to support the detection of aneurysms. The software results are intended to be reviewed after the standard of care image interpretation and are not intended to provide a diagnosis. The device does not alter the original medical images.

2.4. Intended patient population and medical conditions

Sim&Predict software is intended to be used on adult patients undergoing CTA or TOF MRA medical images of the head, regardless of medical condition.

2.5. Contraindications

The contraindications listed below are automatically verified by Sim&Predict during DICOM series import. If one or more of these eligibility criteria are not met, the DICOM series will be rejected and will not be processed by the software. The effectiveness of these verification checks relies on the imported DICOM series conforming to the DICOM standard. Sim&Cure assumes no liability if DICOM series that do not meet this standard are used, thereby causing the verification of these conditions to fail:

- Sim&Predict must be used with a medical exam that has been acquired with the patient in a head-first supine position,
- Sim&Predict must process only CTA images with in-plane pixel spacing (X & Y resolution) of [0.3-0.6] mm,
- Sim&Predict must process only TOF MRA images with in-plane pixel spacing (X & Y resolution) of [0.1-0.8] mm,
- Sim&Predict must process only images with a Z-spacing of a maximum of 1.1 mm.

The contraindications listed below are not automatically verified by the software. Verification of these criteria remains the responsibility of the user:

- Sim&Predict must be used with medical images free of significant motion or imaging artifacts,
- Sim&Predict must be used with datasets comprised only of axial slices,
- Sim&Predict must be used with DICOM that follows the DICOM standard.

2.6. Precautions for use

- The use of the device is not recommended for users with vision disorders.
- Instructions for use must be carefully read and followed before device use.

2.7. Safety Warnings

- The quality of input DICOM images may affect the performance of Sim&Predict.
- Sim&Predict results are intended to assist radiologists after the standard of care image interpretation and are not intended to provide a diagnosis.
- The probability map must be read in parallel with the report issued by Sim&Predict.
- The medical device is in no way to replace a physician's judgment.

2.8. Adverse effects and residual risks

No adverse effect has been identified. The following potential residual risks have been identified:

- Failure in likeliness determination leads to false positives or false negatives, which leads to an increase in diagnosis time and/or impact on the patient care pathway.
- Delayed delivery of results due to software failure or use errors leading to an increase in diagnosis time.
- Failure to properly interpret device results leading to an increase in diagnosis time and/or impact on the patient care pathway.
- Software protection failure regarding cyber threats resulting in corruption of generated results and/or patient data leading to an increase in diagnosis time and/or impact on the patient care pathway.

2.9. Clinical performance

Sim&Predict detects the presence of unruptured saccular brain aneurysms on CTA and TOF MRA medical images with the following performance:

- TOF MRA: Based on a clinical performance validation study on 116 TOF MRA,
 - Sim&Predict detects 94.4% of patients with aneurysm(s) (patient-level sensitivity) and 88.4% of aneurysms (lesion-level sensitivity).
 - Sim&Predict detects 97.9% of aneurysms with a diameter larger than 3mm.
 - Sim&Predict analyzes images in less than 5 minutes.
- CTA: Based on a clinical performance validation study on 193 CTA images,

- Sim&Predict detects 85.9% of the patients with aneurysm(s) (patient-level sensitivity) and 85.4% of aneurysms (lesion-level sensitivity).
- Sim&Predict detects 88% of aneurysms with a diameter larger than 3mm.
- Sim&Predict analyzes images in less than 5 minutes.

2.10. Clinical benefits

Sim&Predict medical device software helps radiologists in identifying unruptured saccular cerebral aneurysms on CTA and TOF MRA medical images participating in the diagnosis process before the management of the disease.

3. Product Description

3.1. Mode of Action

Sim&Predict is a tool designed to assist radiologists in diagnosing saccular unruptured intracranial aneurysms in patients undergoing CTA or TOF MRA imaging as part of routine patient care. The software's step-by-step usage is outlined below:

- 1) **Installation and startup:** Installation of Sim&Predict onto a computer is performed by a Sim&Cure employee, and a connection to the workstation and the licensing platform is established.
- 2) **Query DICOM files:** Sim&Predict software queries the workstation for new CTA or TOF MRA images of the head that are eligible to be analyzed.
- 3) **Image processing and analysis:** A 3D reconstruction of the vessels is generated and analyzed for the presence of saccular aneurysm in the DICOM volume.
- 4) **Probability map generation:** A probability map is generated indicating the likelihood of an aneurysm in different regions of interest. The probability map is designed to be superimposed on the native DICOM images.
- 5) **Report generation:** A report in DICOM format is generated with the findings from the DICOM analysis and screenshots of the regions of interest from maximum intensity projection multiple.
- 6) **Send the results to the workstation:** The probability map and encapsulated PDF report will be sent back to the workstation.

4. Installation & Network Security

4.1. Installation

The installation of Sim&Predict is carried out by the manufacturer Sim&Cure. During the installation process, the Sim&Cure employee configures the connection between the workstation and the computer by performing the following steps:

- Set the port on which Sim&Predict will listen to receive DICOM files
- Set the storage directory that will be created on the computer where Sim&Predict will store DICOM files
- Set the workstation AETitle
- Set the workstation hostname
- Set the workstation port
- Set the Sim&Cure licensing server authorization key

4.2. IT-Network

Sim&Predict must have remote access to the Sim&Cure server. Sim&Predict must have the capacity to access the licensing server at the address *licensing.sim-and-cure.com*. All secure transfers with the licensing server are conducted using port 443. Should further information be required, Sim&Cure can share additional details via the Manufacturer Disclosure Statement (MDS2) document for Network Security Information.

5. User System Requirements

5.1. Supported operating systems

- Windows: 10 and 11 in 64-bit
- Windows Server 2025.

5.2. Minimum hardware requirements



Performances of the software can be altered if the device operates outside the minimal intended operating environment.

The minimum hardware configuration to install Sim&Predict is:

- CPU: Intel 4 cores at 2.0 GHz
- RAM: 8GB
- Free space: 5 GB

5.3. Recommended hardware requirements

The recommended hardware configuration to install Sim&Predict is:

- CPU: Intel i7 6 cores (14th gen, 2023)
- RAM: 16GB
- Free space: 10 GB

6. Instructions for Use

6.1. Start-up procedure

Sim&Predict will be launched when the local server is started. It can also be launched manually using a command line in the terminal if needed.

6.2. DICOM Management

The Sim&Predict software has been developed to automatically monitor the DICOM series on the workstation port. Sim&Predict will only accept the DICOM series if it meets the following criteria:

- For CTA, acquisition protocols TSA and Willis:
CTA Image Storage (SOP Class UID 1.2.840.10008.5.1.4.1.1.2)
- For TOF MRA, acquisition protocols TOF:
MRA Image Storage (SOP Class UID 1.2.840.10008.5.1.4.1.1.4)

DICOM series that do not fit the above criteria will not be supported, and Sim&Predict will deny the retrieval from the workstation.

Once Sim&Predict receives a DICOM series, the software performs a series of checks before opening the DICOM series for processing:

- Minimum slice count: The DICOM series must contain more than 50 slices.
- CTA resolution: In-plane pixel spacing X and Y resolution) must be within [0.3; 0.6] mm.
- TOF MRA resolution: In-plane pixel spacing (X and Y resolution) must be within [0.1; 0.8] mm.

- Maximum Z-spacing: The nominal Z-spacing must not exceed 1.1 mm.
- Z-spacing uniformity: The variance in Z-spacing between adjacent slices must not exceed 0.002 mm. If any of the above criteria are not met, the DICOM series will not be supported, and Sim&Predict will not process it. This will be reported in the log file.

By default, Sim&Predict will continue to queue DICOM series for processing until a maximum of 10 series has been reached. You can set Sim&Predict to have a larger queue size if needed. Once the queue is full, Sim&Predict will not accept any further series. This will be reported in the log file.

6.3. DICOM Series Processing and Report Generation



A report will always be generated and sent, regardless of whether a potential aneurysm was identified. If the software does not identify any potential aneurysms, the report will include the following: labeling, patient information, DICOM data, and a summary of the DICOM processing result stating that no aneurysms were found. However, the probability map DICOM will not be generated in this case.

Sim&Predict will process the DICOM series and identify points of interest, which will then be tagged in the report. A map will be generated to illustrate the probability of an unruptured saccular aneurysm being present, and a report will be generated in all cases, regardless of whether a potential aneurysm was identified. The report will be available for review on the workstation, in the patient study.

Refer to the report examples below for a visual representation of their format and content.

If the DICOM PDF option is selected during the configuration of Sim&Predict:



Sim&Cure
SECURE YOUR TREATMENT

Sim&Predict report

B

General information

Patient name	DATASET306-CT_WILLIS
Date of Birth	Invalid source data
Patient ID	DATASET306
Study UID	1.2.250.1.38.2.1.102.201013143213.110558832
Series UID	1.2.840.113619.2.340.3.413931696.647.1602820981.755
Study date	2020-01-01
Report date	2026-06-23
Probability map series UID	

C

Results

2 POTENTIAL ANEURYSM(S) FOUND

A



Sim&Cure
95 rue Pierre Flourens - Bâtiment H
34090 Montpellier FRANCE
2026-06

The instructions for use must be read.

See warnings in the Instructions for use before using the device.

LOT 2.0.0

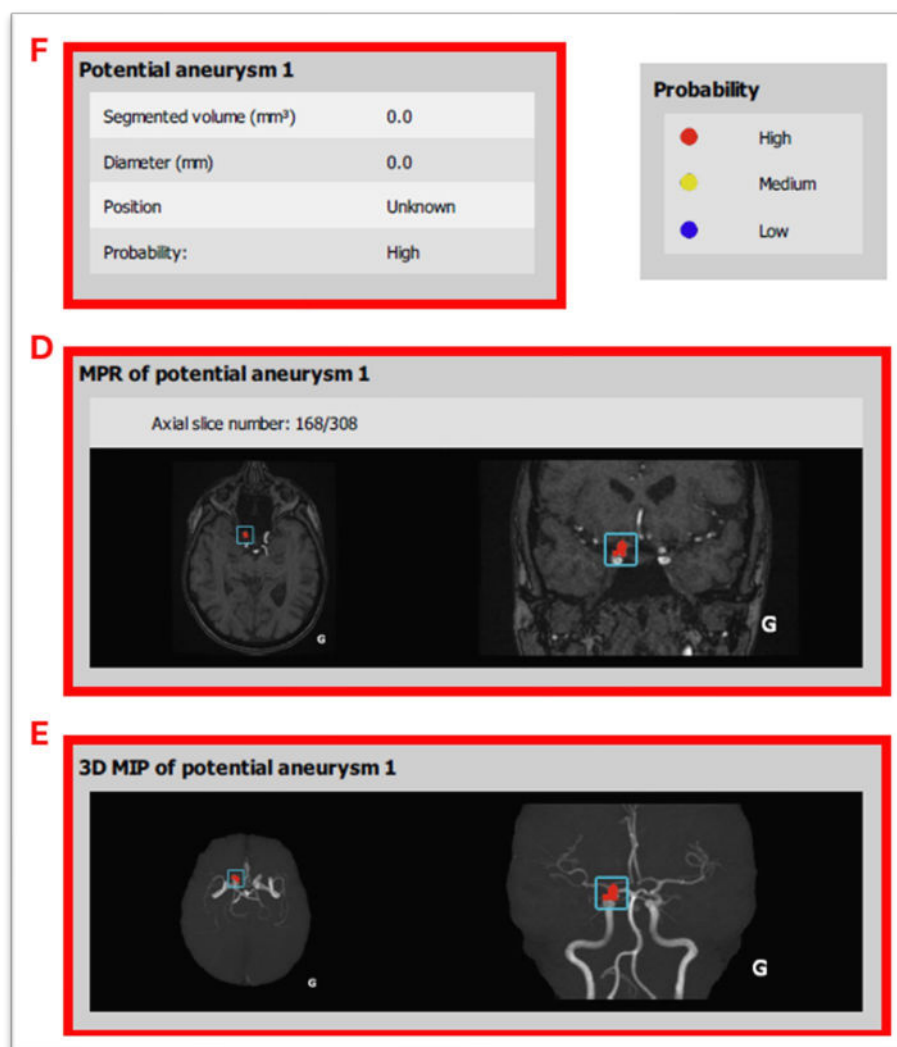
UDI (01)034665786000117(11)260623(10)2x0x0

<https://sim-and-cure.com/professionals/>
Password: Simandunlock

MD Medical device software for computing the probability of neurovascular aneurysm(s)

%ONLY

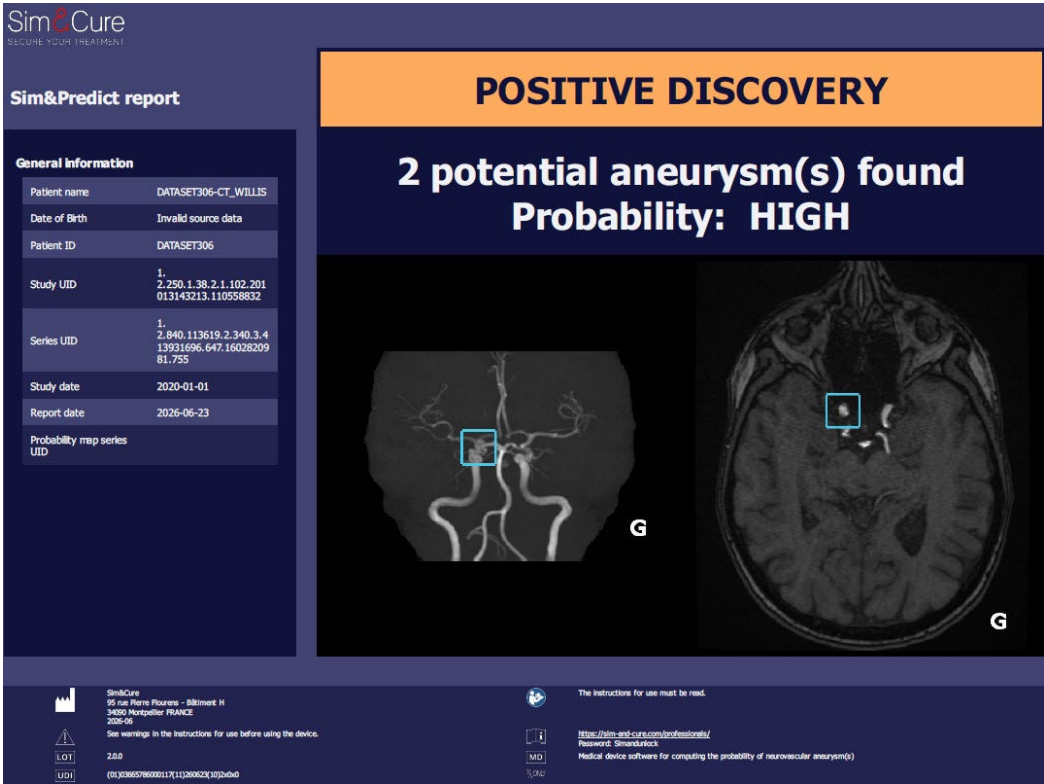
- A. Sim&Predict label, content depending on the user's geographical area.
- B. General DICOM and patient information, and report creation date.
- C. Summary of DICOM processing and analysis results.



- D. Axial and coronal multiplanar reconstructions of the volume, including the suspected aneurysm(s) (if any).
- E. Axial and coronal 3D maximum intensity projection reconstructions.
- F. The volume of the suspected aneurysm (in mm³), characteristic diameter of the suspected aneurysm (in mm), and the location of the suspected aneurysm. This location can be determined as ICA, MCA, ACA, PCA, Basilar, ICA terminus, or Basilar terminus.

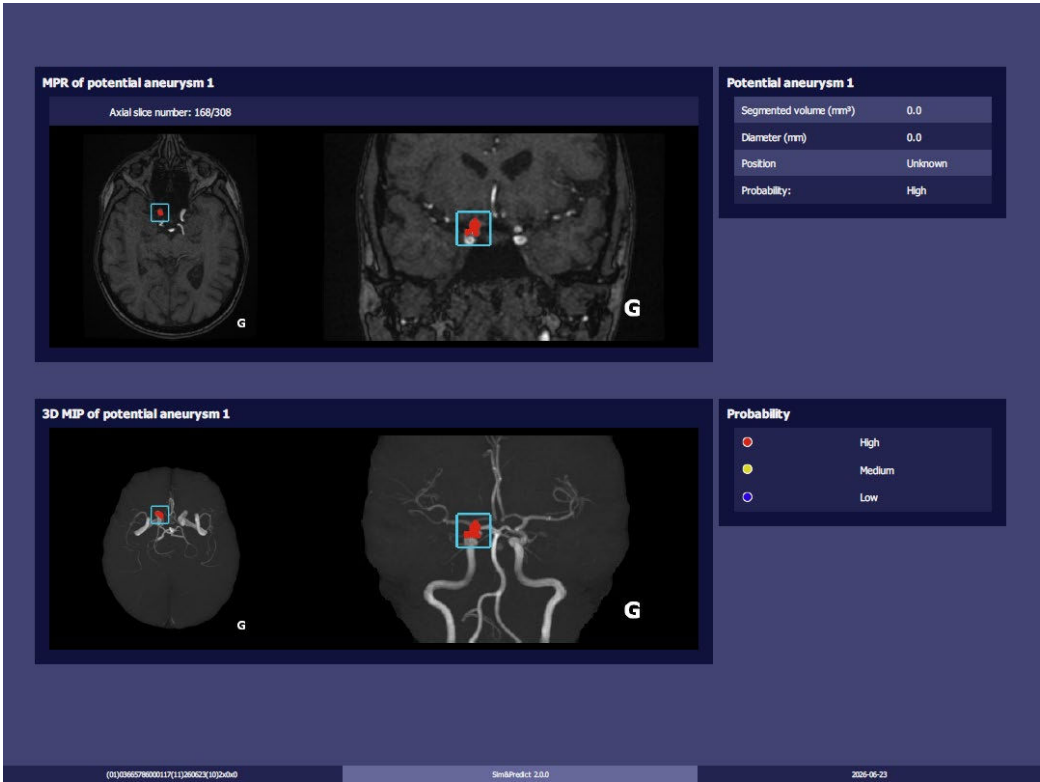
Each page will contain the probability information for one aneurysm. In instances where the likelihood of multiple aneurysms is suspected, supplementary pages will be incorporated into the report to indicate the probability of the presence of those potential aneurysms.

If the DICOM SC option is selected during the configuration of Sim&Predict:



The general information section remains unchanged, containing general DICOM and patient information, and the report creation date. The report also contains a summary of DICOM processing and analysis results.

In instances where multiple aneurysms are identified, as illustrated in this example, the initial page will present the finding with the highest probability. The ensuing pages contain further information on each finding, including:



In the event of no findings, a unique page will be made available:



6.4. Probability color map

The color map employed in the report delineates the various probability ranges of the detected aneurysm. The colors are defined as follows:

- High (red): There is a high probability of an aneurysm at the pointed location.
- Medium (yellow): The numerical model suggests a moderate probability of an aneurysm at this location.
- Low (blue): The presence of a suspicious shape. The presence of an aneurysm at the pointed location is a possibility.

7. Removal procedure

7.1. Uninstallation

The uninstallation process is conducted by Sim&Cure. The Windows service associated with Sim&Predict will be removed.

7.2. Decommissioning

The software does not store health data. Following the uninstallation process, the Sim&Cure employee will proceed with the configuration of the user profile and associated device, setting them to disabled status on the Sim&Cure licensing server.

8. Cybersecurity



The healthcare organization's IT administrator is responsible for ensuring a secure operating environment for Sim&Predict. In particular:

- Access to the workstation or server hosting Sim&Predict shall be restricted to authorized users. Failure to do so may result in unauthorized access, software corruption or interruption, and unauthorized access to log files containing sensitive patient information.
- Communications with the PACS shall be secured (e.g., via an internal protected network or a VPN). Failure to secure communications may expose sensitive patient data to interception or modification through man-in-the-middle attacks.

The use of Sim&Predict does not require specific training and experience in cybersecurity.

8.1. Anomalous conditions announce

Sim&Predict does rely on network connections. Punctual communications are established to maintain Sim&Predict enabled state. Security events, such as unexpected replies from the server, are logged in the log as a 'Warning'. The journalization of software events is available through the log file folder.

8.2. Log files

The actions performed by Sim&Predict, as well as connections to the licensing server, are logged in a log file. This log file is named 'out.log', which is present in the Sim&Predict folder of the version created during installation. Any errors, warnings, debugs, and user information that occur are logged. The privacy data it might contain will be encrypted.

8.3. Configuration restoration by an authenticated privileged user

The usage tracking is done by a licensing server. To restore a configuration, please contact Sim&Cure for a Sim&Cure employee to perform software maintenance to ensure that all items set during installation are reconfigured correctly.

8.4. End of support

The Sim&Predict software is supported for two years, and it is recommended to update it as soon as a new version is available. Finally, after two years, access to the software will be disabled by deactivating the device license on the licensing platform. The licensing platform can identify the user's versions. As a result, obsolete versions would be deactivated. In addition, the Sim&Predict software is supported as long as the operating system on which the software is installed is supported by its manufacturer.

8.5. Malware detection

A malware detection is performed on the installation package, which ensures that the installed software is free of malware.

8.6. Antivirus

For security reasons, an up-to-date antivirus program must be kept on the computer at all times.

8.7. Private data

To update its usage data, Sim&Predict must connect with the licensing platform at least once a day. The connection is secure and encrypted and does not transfer any private data during the process, only Sim&Predict internal data, which allows it to function correctly.

8.8. Firewall

An internal or external firewall should be configured by the IT department to minimize the risks of unauthorized network access, attacks, DDoSing, or tampering while the software is being used.

8.9. Operating system updates

The computer must be kept up to date and secure by applying the recommended security updates from the OS vendor.

8.10. Sim&Predict update

Make sure that the security patches provided by Sim&Cure are properly and regularly installed by the IT department to have the latest development and security fixes.

8.11. Obsolete operating system

Operating systems no longer receiving security updates are considered unsupported and may pose security risks. Users are responsible for keeping their systems up to date. Regularly upgrading to the latest supported versions is strongly recommended to ensure system security.

9. Software updates



The installation of Sim&Predict updates is compulsory to guarantee the reliability of the results and patient safety.

The update phase for the Sim&Predict medical device provides the user with the benefit of the latest software version and any improvements made. In the event of a new version of the software becoming available, Sim&Cure will notify the user by email and/or telephone to arrange a suitable update meeting.

 Sim&Cure
95 rue Pierre Flourens - Bâtiment H
34090 Montpellier - FRANCE
2026-08

LOT 2.0.0