

# Sim&Size

TO IMPROVE THERAPEUTIC PLANNING

## SIM&SIZE 2.1.1 USER RELEASE NOTES

### US REGION



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# Abstract

These release notes provide an overview of the changes, enhancements, and corrections introduced in Sim&Size™ 2.1.1 software as a medical device. This product is intended to provide a 3D view of the final deployment of intrasaccular devices, flow diverters, stents, and coils for endovascular treatment of cerebral aneurysms.

Any suggestions or corrections are appreciated and can be sent to :

✉ [contact@sim-and-cure.com](mailto:contact@sim-and-cure.com)

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# What's New in Version 2.1.1

Sim&Size™ 2.1.1 introduces more advancements to procedural readiness and simulation fidelity. Driven by clinical collaboration, these updates optimize treatment planning workflows and provide deeper insights through advanced modeling and data metrics.

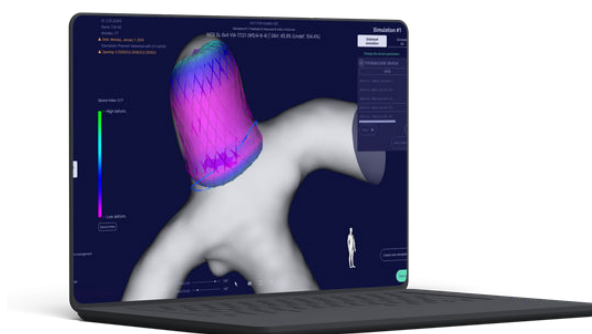
For a comprehensive understanding of the product's full capabilities, we recommend consulting the instructions for use.

## Procedural Optimization

- **Fast, Automated Workflow:** “Hyperspace” mode allows device simulation to start upon patient selection, enabling faster access to simulation while retaining full control.
- **Advanced Mechanical Modeling:** High-fidelity simulation of complex device behaviors—including more representative WEB™ recess behavior.

## Advanced Insights & Integration

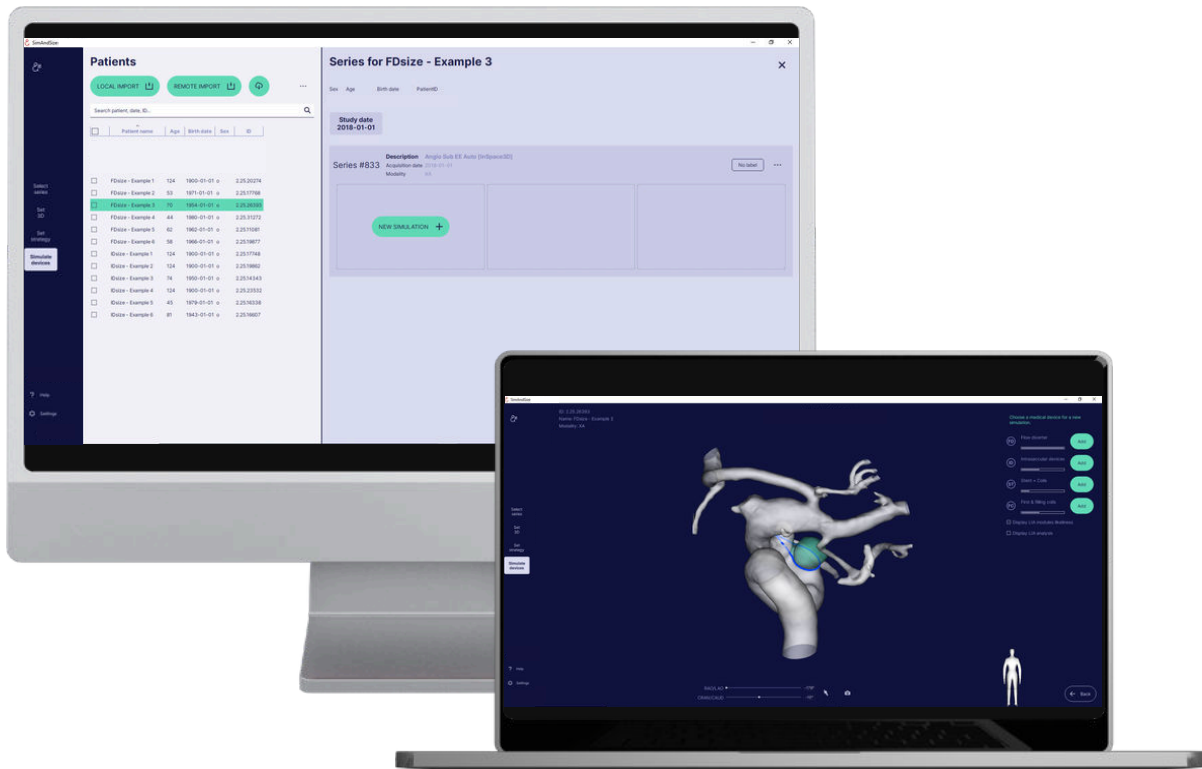
- **Dynamic Apposition Bar:** The new dynamic bar adjusts automatically to reflect the distribution of wall apposition along the device to offer an instant visual summary of apposition distribution for intrasaccular devices.
- **Advanced Device-Specific Metrics:** Device models now include advanced data such as relative sizing, local pore density, DAV ratio, and the Spruce Index to support more informed objective decision-making.
- **Expanded Multi-Device Simulation:** Y-stenting has been integrated with our existing capabilities—such as telescoping, stent/coil, or flow diverter/coil combinations—allowing for a broader simultaneous comparison of treatment strategies, devices, and sizes.
- **Seamless Connectivity:** Features include TOF-MRA pre-planning, DICOM node pushing, and overlay of the simulated device with live angiography to facilitate continuity between pre-procedural planning and intra-procedural visualization.



## Technical Specifications & Compatibility

- **OS Support:** Sim&Size™ 2.1.1 is compatible with macOS Tahoe (26.x). Please note that support for macOS Ventura 13.x has been deprecated.
- **Device Library:** This version includes the latest size database for the Terumo Neuro Woven EndoBridge (WEB™), with the enhanced high-fidelity simulation of recess behavior.

Together, these improvements provide powerful new tools to support the planning of endovascular treatment strategies for cerebral aneurysms.



# Fixed Bugs

## User Interface

Description
Addressed minor user interface glitches.
Fixed the display of incorrect or missing message when a specific operation occurred.
Fixed the display of saved simulation thumbnail.
Enhanced software stability to reduce unexpected crashes and errors.
The number of visible studies per patient is no longer limited.
Fixed windowing error in some cases.

## Functional Errors

Description
Enhanced software stability to reduce unexpected crashes and errors.
Corrected report data to ensure accurate information.
Exported DICOM files are no longer deleted when Sim&Size is closed.
The initialization of the region of interest now functions with NATFILL images.
Fixed compatibility issues with imported series from legacy databases.
For multi-device simulations, all devices are now correctly exported in .dcm or .vtp format.
Fixed issues related to distal and proximal point handling, including rendering of distal points and device simulation.
Fixed an error where modifying the region of interest was blocked after replaying a simulation in some cases.
Fixed the display of incorrect or missing message when a specific operation occurred.
Corrected report data to ensure accurate information.
Saving option has been fixed to ensure all simulations are recorded.

# Fixed Bugs

## Cybersecurity

Description
Hardened software security to prevent unauthorized access.
Corrected importation of some series with anonymization

## Device Simulation

Description
Corrected display of the deployed length.
Corrected position of the coil in some simulation with coils and intrasaccular devices.

# Known Issues & Limitations

## User Interface

Description
Minor visual artifacts may appear in some cases.
Device visualization or deployment issues (e.g., incorrect proximal/distal handling, failure after an image fusion).

## Functional Errors

Description
Simulation interaction may occasionally experience delayed rendering or temporary freezing.
Reports generated may occasionally show incomplete data or incorrect screenshots.
Studies imported from PACS or local DICOM files may be slower or fail for some formats or character sets. Invalid database paths can also prevent access to stored cases.
The software may unexpectedly close or freeze in specific contexts.

# Contact

For further information about the changes described, please do not hesitate to contact our support team. You can reach us via email or phone, and we will do our best to help you.

✉ [contact@sim-and-cure.com](mailto:contact@sim-and-cure.com)

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We invite you to start your Sim&Size experience.

Discover how Sim&Size can benefit you and your patients by visiting our website or contacting us today.



<https://sim-and-cure.com>



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**Sim&Cure**  
SECURE YOUR TREATMENT

In accordance with the US regulations, Sim&Size™ software is an FDA-cleared medical device, classified as class II, and is intended for healthcare providers.

Sim&Size™ enables the visualization of the patient's cerebral blood vessels and the computationally modeled placement and apposition of neurovascular implantable medical devices for preoperative planning of neurovascular interventions. Information provided by the software is not intended in any way to eliminate, replace, or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition. Read the instructions for use carefully before use.

The use of Sim&Size™ is contraindicated in the following cases:

- in the event of giant intracranial aneurysms involving poor reconstruction of the deployment zone.
- in the presence of artifacts in the planned implantable medical device deployment zone.
- when there is a possible contact of an implanted device with the simulated implantable medical device in the deployment zone.

This communication only concerns the USA market. It should be noted that market authorization can differ depending on your location, so please contact us for more information