LATAM User Release Notes Sim&Size 2.1.1

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Sim&Size

TO IMPROVE THERAPEUTIC PLANNING

SIM&SIZE 2.1.1 USER RELEASE NOTES

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Contents

Sim&Size
TO IMPROVE THERAPEUTIC PLANNING

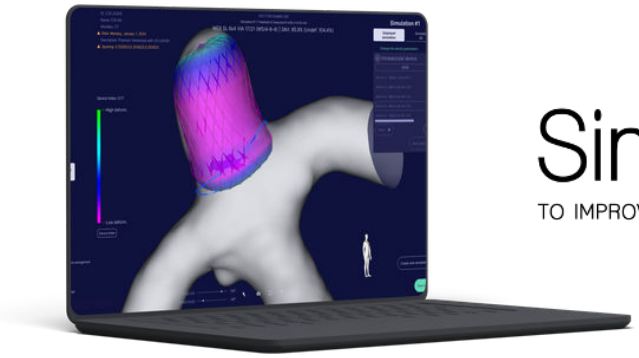
Product Description

Sim&Size™, Software as a Medical Device (SaMD), supports cerebral aneurysm treatment strategy development aligned with individual physician needs. It enables deliberate intra-procedural decision-making and supports physicians in complex cases. Visualize and compare treatments and devices—such as intrasaccular devices, flow diverters, stents, and coils—to support informed decisions across planning and procedure.

Key Capabilities

To support these informed decisions, the computational modeling platform enables:

- **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 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.
- **Multi-Device Simulation**: Integrated features—including Y-stenting, telescoping, and stent/coil or flow diverter/coil combinations—allow for the 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.



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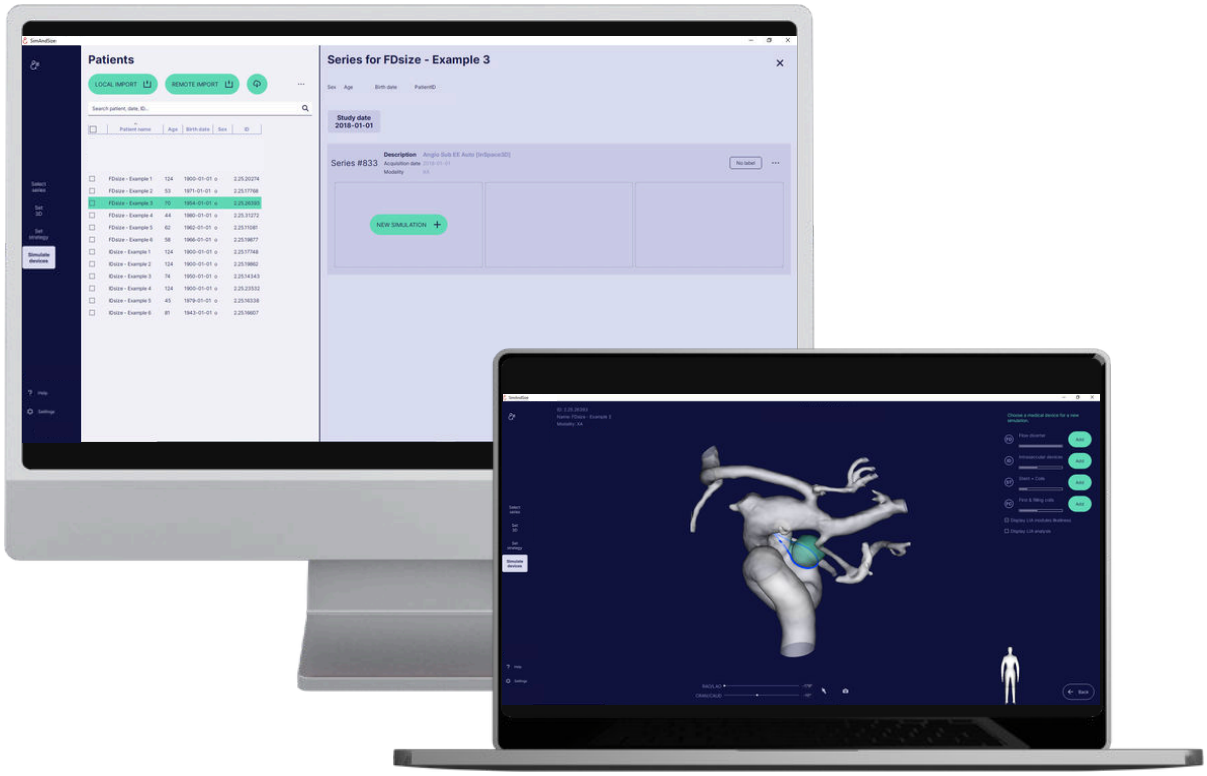
Technical Specifications & Compatibility

- **OS Support**: Sim&Size™ 2.1.1 is compatible with Windows 10 and 11, macOS Sonoma (14.x), Sequoia (15.x), and Tahoe (26.x).
- **Network**: Supports integration with hospital DICOM nodes for seamless data transfer.

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



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 capabilities 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

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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&Size™ is a medical device software 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.

Sim&Size™ shall be used exclusively in accordance with the Instructions For Use in force.
Sim&Size complies with relevant applicable regulations. Please contact Sim&Cure for more information on the availability of Sim&Size in your country.

Regulatory information:

- ANVISA registration number: 81464750127
- INVIMA registration number: INVIMA 2022DM 0026291