



**GALAXY**

**User Manual Addendum**

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GALAXY

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# Galaxy System User Manual Addendum

This addendum to the Galaxy System User Manual provides additional guidance on symptoms of potential system failures and recommended user actions to address such failures.

This IFU addendum applies to the Galaxy System (GAL-001), Galaxy System Software version 1.1.1.1-15 (1C.1).

Keep this addendum with your Galaxy System User Manual.

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# Galaxy Setup Guidance

During system setup, there are graphics and animations that accompany the on-screen instructions in both Abbreviated and Guided Setup.



**CAUTION:** If any on-screen abnormalities are observed during the setup workflow, such as missing graphics or static animations, the system should be rebooted to avoid system failure. Failure to restart the system upon observation of abnormal system behavior may result in forced system restart and the need to repeat some portions of the procedure.

See *Abnormal System Behavior* section of *Appendix A* for further instructions.

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# Performing a Procedure

Each procedure consists of tasks and each task has one or more steps. In performing a procedure, you will typically perform the following steps:

1. Load a Procedure.
2. Register.
3. Navigate to the lesion.
4. Perform the TiLT<sup>+</sup> workflow.
5. Align the Galaxy Bronchoscope with lesion.
6. Insert the biopsy instrument.
7. Obtain biopsy.



**CAUTION:** If any on-screen abnormalities are observed during the procedure, such as missing graphics or static animations, the system should be rebooted to avoid system failure. Failure to restart the system upon observation of abnormal system behavior may result in forced system restart and the need to repeat some portions of the procedure.

See *Abnormal System Behavior* section of *Appendix A* for further instructions.

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# TiLT<sup>+</sup> Technology

Galaxy System Tool in Lesion Tomography, or TiLT<sup>+</sup> Technology, enables the generation of a partial 3D reconstruction of the lung. The TiLT<sup>+</sup> workflow includes a series of steps including image acquisition, scope tip and lesion selection, and image reconstruction.



**CAUTION:** If any on-screen abnormalities are observed during the TiLT<sup>+</sup> workflow, such as missing graphics or failing animations, the system should be rebooted to avoid system failure. Failure to restart the system upon observation of abnormal system behavior may result in forced system restart and the need to repeat some portions of the procedure.

See *Abnormal System Behavior* section of *Appendix A* for further instructions.

# Appendix A

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## Abnormal System Behavior (During Procedure)

*Abnormal* may be identified by lagging images, missing graphics/animations, missing video replay, or other unexpected behavior.

1. When safe to do so, remove instruments inserted in the working channel of the bronchoscope.
2. Use the Galaxy Controller to relax and then retract the bronchoscope. If the bronchoscope or controller cannot be robotically controlled, skip to step 3.
3. Detach the bronchoscope from the scope drive.
4. Reboot the system.
5. Follow on-screen instructions to proceed with setup and continue the procedure.
6. Contact Noah Medical Customer Service for support if abnormal system behavior persists after system reboot.



**CAUTION:** Failure to restart the system upon observation of abnormal system behavior may result in forced system restart and the need to repeat some portions of the procedure.

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# Customer Support

Only qualified service personnel should service or maintain hardware components. If you feel that the Galaxy System hardware components or associated features or functions do not perform as expected, or they provide results that are inconsistent with your established clinical and research protocols, contact Noah Medical Customer Service at +1-888-325-NOAH (6624).