Simplant Editor 3.1 – List of Known Software Issues

Project Title:	Simplant Editor 3.1
Software Build #	3.1.0.42

LIST OF KNOWN ISSUES / DEFERRED BUGS

All issue listed in the table below are inherited from previous versions of the device. There are no new Known Issues reported for Simplant Editor 3.1 according to verification and validation results.

The decision to not fix the bug in the scope of the SIMPLANT Editor 3.1 project is based on a risk assessment for the patients and operator.

For all remaining issues listed in the table below:

1. a new row has been added in the SIMPLANT Editor 3.1 – Risk Register to evaluate the potential harm the remaining issue may bring to the operator or patient. From this risk analysis all items are considered safe.
2. a severity rating has been assigned to each issue based on the impact on the device performance:

Severity/ Impact on device performance	Definition
Low	The application can be used even with the bug, the delivered scope is not affected but the behaviour is in principle not optimal.
Medium	The bug prevents normal or expected operation but there is a workaround.
High	The bug prevents normal or expected operation and there is no workaround.

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Critical	The application behaves completely incorrectly (crashes, hangs, blocks other functionality) when this issue occurs and there is no workaround.

LIST OF KNOWN ISSUES / DEFERRED BUGS

Title	Comment
Positions of 3D objects and positions of slices from DICOM dataset do not match for planning files prepared using non-RAB orientated DICOMs	Affects rare scenarios when patient scanned with non-RAB orientation. **Workaround** - Design Service team will put case on hold asking clinician to deliver new scan data with RAB orientation of DICOMs. **Conclusion**: Issue will not be fixed as customer informed (IFU) to send DICOMs with RAB orientation.From risk analysis item is considered as safe.
SIMPLANT Editor crashing on click on "Open archived planning" button on some DELL laptops with "Dell Backup and Recovery" software installed	Official known issue of SOUP component: "Dell Backup and Recovery" software from DELL impacts behaviour of other software developed on QT framework. According to QT issue bug tracker – issue is reported to DELL officially. Meanwhile - simple **workaround** is available: user can use drag'n'drop to open archived planning file. **Conclusion**: We don't plan to fix the issue for current version. From risk analysis item is considered as safe
[MAC OS] Application doesn't recover network connection automatically if it got lost and reenabled	Not influence on clinical side. This is judged a very unlikely situation. Meanwhile, clear **workaround** is also available - user just need to restart the application.

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again	**Conclusion**: We don't plan to fix the issue for current version. From risk analysis item is considered as safe
Incorrect transparency results on 3D view with some Intel's HD Graphics cards (Ivy Bridge Generations: HD4000 + HD2500)	Not influence on clinical side This is *not* occurring on all Intel HD graphics systems. Issue reproduced for Intel HD2500 and HD4000 - Both are the same generation video card: Ivy Bridge "Six generation" of Intel's HD graphics. Release in 2012. **Workaround** is available – user can review objects properties and location on 2D view. **Conclusion**: We don't plan to fix the issue for current version. From risk analysis item is considered as safe
Application might crash on Win-32bit OS if open planning file with a large set DICOM images (which requires 1.5 GB of memory or more)	This issue only manifests for users with a PC's with minimal system specs that opens planning file with very large scans As a **workaround** User can user computer with recommended system configuration. **Conclusion:** We don't plan to fix the issue for current version. From risk analysis item is considered as safe