

Exablate 4000

Release Notes and Errata

For Type 1.0 & 1.1 Systems with WS Version 7.33

These Release Notes & Errata cover the Exablate SW version 7.33 for Exablate 4000 Type 1.0 & Type1.1. The document is divided into two chapters:

- Chapter One provides the release notes
- Chapter Two identifies errata information

Please read this document as it contains important information relevant to your equipment and software

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1. Release Notes

Purpose and scope

This chapter specifies the new primary features in Exablate 4000 software version 7.33 (in relation to the previous version: SW version 7.3) and details the relevant instructional documents.

New features

- Added support for Exablate Type1.0
- Added Generic MR interface
- Added Max TG handling mechanism
- Added support for local TG calibration (for GE DV 26 or higher)
- Implemented improved movement detection algorithm
- Added support for Windows 10 based systems

Adjustments

- Auto populating of single exam to image loading dialog
- Highlighting active Exam in exam search result window of image retrieval dialog
- Image retrieval supported for 1024x1024 resolution as well, and for anonymized images
- Removed requirement to place fiducial to proceed from planning to treat stage
- System allows active cleaning circulation while MR is scanning

Applicable Documents

The instructions for use and user guidelines for Exablate 4000 Type 1.0 & 1.1 software version 7.33 can be found in the following documents (English version source documents):

Document Number	Document Title
PUB41005062	Exablate 4000 Types 1.0 and 1.1 SW7.33 Operator Manual (NON-CE)
PUB41005064	Exablate 4000 Types 1.0 and 1.1 SW7.33 Operator Manual (CE)

All applicable documents revisions shall be effective for date of document approval.

2. Errata

Purpose and Scope

This chapter identifies known problems or issues in this software release. We present general guidelines of software use, in addition to problem descriptions (What Happens) and solutions (Workarounds) resolving the problems.

Troubleshooting guide:

Graphic User Interface

1. **What Happens:** When opening the Image retrieval dialog, the dialog text of MR and Device status (display) appears partially cut/incomplete (e.g. – “Connection e” instead of “Connection error”)
Also, the status text does not update while the dialog is open.
Workaround: Refresh display by moving the “Image retrieval dialog” window away from the text. Close the dialog to get an updated status message
2. **What Happens:** Cannot dismiss pop-up message
Workaround: To dismiss the submenu, press on the main image window first and then proceed to dismiss the message

General issues

3. **What Happens:** If the workstation computer is reset during a “download anonymized export” operation, the ability to export that treatment may be lost (not the treatment data itself)
Workaround: Do not reset the workstation PC during anonymized export operation.
Note: Failure during non-anonymized export has no such problem
Note2: In case this happens, contact Insightec support

Image Retrieval

4. **What Happens:** An error message appears when attempting to retrieve an image series
Workaround: Try to retrieve a range excluding the 1st and last image.
Some image series (in particular reformatted series) may include a “Scout image” which contains information about the series. It is often the first or the last image of the series. You can also delete this image from the series on MR before retrying to retrieve the series.

5. What Happens: A loaded series is recognized as belonging to the wrong orientation (Axial\Sagittal\Coronal)
- Workaround: This may also result from a “Scout image” in the series, which contains different information. Retrieve a range excluding this image or delete this image on the series on MR before retrying to retrieve the series. Observing the series on the MR console can help identifying the scout image and its index.

Water system

6. What Happens: The PPM value (as shown on the water system display and status bar) is stuck at 9.99 (does not decrease while circulation is on)
 This could be due to air stuck in the circulation system.
- Workaround:
1. Perform full drain
 2. Set system to “Degas” mode
 3. Degas - circulate for ~30 seconds
 4. Proceed with treatment circulation
7. What Happens: The water system status bar reports “Error”, following full drain of water.
- Workaround: Pressing the (blue) reset button once or twice should rectify the issue.
 Note: To prevent the issue from recurring, make sure circulation is paused before draining water by pressing the blue button on the water system controller and verifying the little green light on it is turned OFF.
8. What Happens: The water system status bar reports “Error” when attempting to circulate the after red air release button has been used to release air bubbles.
- Workaround: Pressing the (blue) reset button once or twice should rectify the issue.
 Note: To prevent the issue from recurring, always perform a short fill action after using the red pressure release button. This defines a new set point for the water system’s pressure sensor.

Planning Tools

9. **What Happens:** Replacing of planning MR images causes fiducials added on CT or Pre-op to be deleted.
Note: When removing or replacing CT images, the fiducials drawn on Live MR are not deleted.
Workaround: Start drawing objects (excluding AC-PC-Midline) after planning images have been acquired. Add fiducials if missing.
10. **What Happens:** The automatic sinus detection algorithm marks parts of the skull as a non-pass region.
Workaround: Delete the automatic markings and mark the sinuses manually using the “draw Polygonal NPR” button
11. **What Happens:** In planning-session, an error message is displayed when attempting to Reformat the CT (For SDR calculation when no Pre-Op MR is available): “Non aligned CT images cannot be reformatted” And reformatting is not available.
Workaround: To allow SDR calculation for non-aligned CT scans, load the pre-made planning-session called “DUMMY”, which contains placeholders for the Ax\Cor\Sag MR planning images. See **appendix A** for detailed instructions.
12. **What Happens:** Midplane line does not appear during treatment, when placed on unregistered Pre-Op MR
Workaround: Perform registration or add AC-PC-ML markings to Live MR images.
Explanation: Midline plane is displayed only when it exists on MR Live images. For example, if AC, PC and ML are added on Preop images, the midplane will not be shown until the registration to Live MR images is done.

Miscellaneous

13. **What Happens:** Status bar freezes while image retrieval\export dialog is open
Workaround: Close dialog
14. **What Happens:** Dedicated technical export button fails to export file
Workaround: Extract the summary from the treatment export file

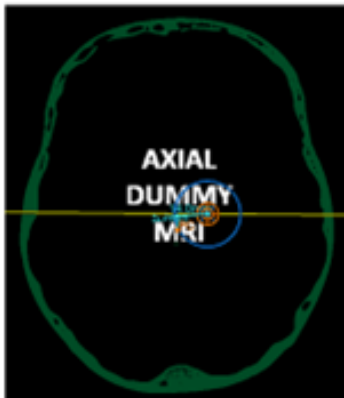
On certain configurations only (e.g. on Win10 based systems)

15. What Happens: Cannot burn treatment export to CD
Workaround: Export to a USB device. Note that any USB device used for connected to the Exablate workstation requires a prior malware scan
16. What Happens: Rarely, image strips will disappear
Workaround: Enter and exit "UTILS" menu. If that fails to help, open and close Image retrieval dialog ("ARCHIVE")

Appendix A

Calculating SDR for non-Aligned CT series

- When trying to reformat the CT for SDR calculations, a message may pop up: “Non aligned CT images cannot be reformatted”. This error occurs with some CT reconstructions, where the slice stack is angled (/////)
so that it does not form a box (|||||)
- If this occurs, skip the CT reformat step and perform the following:
 - Load the dummy treatment plan provided by INSIGHTEC (blank MR images)
 - Run the automatic registration – adjust so green CT overlay is roughly centered
 - Place AC and PC on the CT
 - Click “AC-PC Target” or place a fiducial on the CT at the desired target location
 - Place target on MR Axial at the location of AC-PC Target or the CT fiducial
 - Align the transducer on each plane of MR, according to the green CT overlay
 - Proceed with the nominal SDR workflow
- **CT reformatting is only needed for SDR calculations, not for treatment**
- The described workflow assumes that MR pre-op images are not yet available for the patient. If these are available, they can be used and there is no need to reformat the CT
- As with reformatted CT images, be sure to delete or replace the dummy MR images prior to treatment
- If there is any need for assistance, please contact your INSIGHTEC representative



Appendix B

Insightec internal serial numbers for some of the described issues.

#	Internal ID
1	ID 28478
2	ID 26904
3	ID 26803
4,5	ID 28611
9	ID 26772
10	ID 27103
11	ID 26465
12	ID 26544
13	ID 29901
15	ID 29899
16	ID 29894, ID 29897