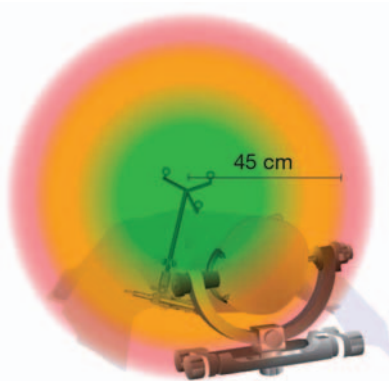


MEASURES TO IMPROVE CRANIAL NAVIGATION ACCURACY

Brainlab Cranial Navigation System



1. POSITION REFERENCE ARRAY CLOSE TO REGION OF INTEREST

The closer the array is mounted to the actual region of interest, the more accurate the procedure. Position the reference array as close to the region of interest as possible, without the array interfering with the necessary surgical space.

Do not exceed a distance of 45 cm between the region of interest and reference array.



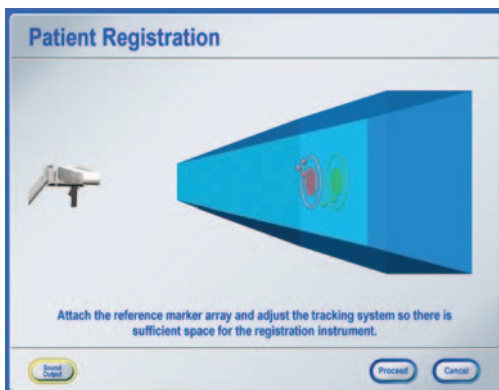
2. MINIMIZE CHANGES OF CAMERA POSITION

Select an initial camera position that will work throughout the entire case including registration and navigation. Avoid major changes of the camera position. Optimize the room setup prior to registration. Ensure that:

- The reference array remains visible for the entire procedure.
- The line of sight between reference array and camera will not be blocked, e.g., by a microscope.
- Reference array and region of interest are in the center of the camera field of view. This can be verified in the **Tracking System Alignment** dialog. Press one of the camera view windows in the menu bar to open the dialog.
- The distance between camera and region of interest is 1.5 m +/- 0.3 m.

If the camera has been moved, verify the accuracy as described in steps 8 and 11 of this document.

When performing a biopsy, be aware that the patient's head (or drapes or other parts of the OR setup) may easily obstruct the visibility of the Brainlab biopsy system. In order to avoid having to move the camera during the surgery, ensure already during registration that the Brainlab biopsy system and the Brainlab biopsy needle with flat markers will be visible later on.

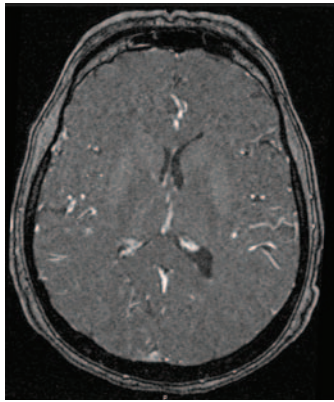


3. ENSURE RIGID FIXATION OF PATIENT IN HEADHOLDER

Relative movements of the patient's head within the headholder cannot be compensated by the Brainlab cranial navigation system.

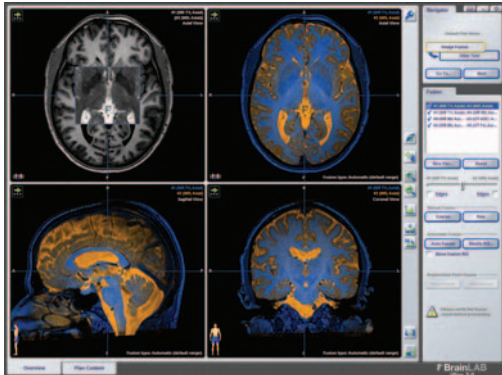
- Choose a stable headholder and check that it is not possible to move the patient's head in the headholder.
- Ensure that the patient's head does not slide down during the procedure.





4. ENSURE APPROPRIATE PATIENT SCANS ARE USED

- Acquire all data sets, especially the one used for registration, according to the Brainlab scan protocol.
- Always ensure 3D distortion correction at the MR scanner control station if available.
- For surface registration: Compare the patient's face with the 3D reconstruction. Avoid areas that differ between the real patient surface and the 3D image in the software reconstruction. Possible sources of error include MRI headphones pressing into the skin during the scan or tubes and tape on the patient, which change the skin surface.



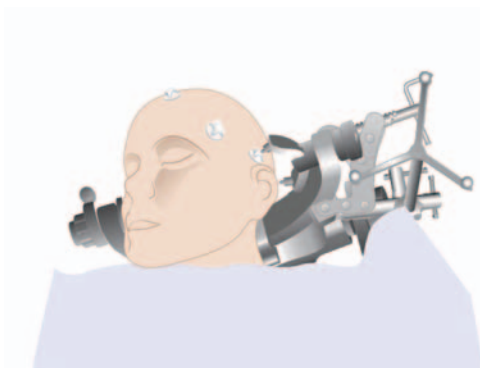
5. ENSURE ACCURATE IMAGE FUSION

- Verify each image fusion carefully by using the spy glass and amber/blue views.
- Make sure that you verify various anatomical landmarks distributed throughout the whole image volume.



6. USE NEW, CLEAN AND UNDRAPED MARKER SPHERES

- Use new marker spheres for all unsterile and sterile instruments and reference arrays.
- Do not use dirty, damaged, wet or covered marker spheres.
- Ensure correct mounting of the marker spheres.
- Do not re-sterilize disposable reflective marker spheres.



7.a) STANDARD REGISTRATION

Ensure appropriate placement of registration markers

- Use at least 6 - 7 markers for registration.
- Ensure that the position of the registration markers on the skin will not change (if necessary draw circles around markers).
- Avoid areas that the patient is laying on or where skin shift is likely.
- Do not place markers close to each other; rather distribute them over the head.
- The region of interest should be surrounded by the registration markers.
- When planning donut markers in the software, ensure that the registration point is placed in the center of the donut marker on the skin surface in each of the axial, coronal, and sagittal views. Use **Softouch** for point acquisition if available.

MEASURES TO IMPROVE CRANIAL NAVIGATION ACCURACY

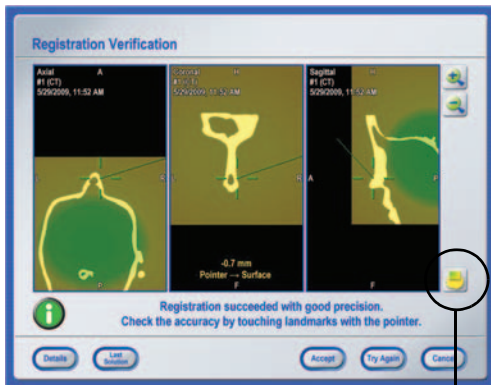
Brainlab Cranial Navigation System



7.b) SURFACE MATCHING REGISTRATION

Ensure appropriate point distribution

- Acquire points on distinctive surfaces and bony structures (see green areas in image on left side).
- Always include the entire profile of the nose including left and right sides.
- Acquire points on both sides of the patient's head.
- Avoid taking points on indistinctive, rounded areas like the dome of the head.
- Spare the eyebrows and areas where skin has visually shifted.



8. DETAILED VERIFICATION BEFORE DRAPING

The actual accuracy of the system can only be determined by the user, who, after verifying the accuracy, decides if it is suitable for the current procedure. Even if the registration succeeded with good precision, be aware this is only information on how well the software was able to match the acquired points to the planned markers and landmarks. Always verify the accuracy using the **Pointer** or **Softouch**:

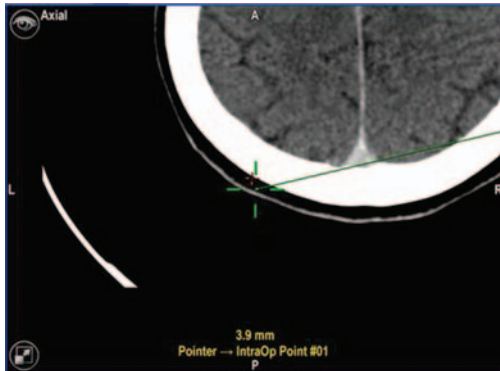
- Verify in areas where no points were taken during registration.
- Verify in multiple widely distributed areas, e.g., on both sides of the face, at the top of the head, in or near to the region of interest.
- Rotational errors can only be detected when verifying at significant landmarks all over the patient's head. Recommended landmarks are e.g.,:
 - Tragus left and right
 - Inion (postero-inferior part of skull)
 - Bregma (top of skull)
 - Teeth in upper jawTypical landmarks are also nasion or lateral canthi, but these may show an overly optimistic result when using surface matching, as they are in the same area where registration points were acquired.



The accuracy in the region of interest may differ from the accuracy verified on the skin surface. To estimate the accuracy in the region of interest, use the anatomical landmark verification in combination with the reliability map feature (availability of this feature depends on your product version, see icons on the left).

9. ACQUIRE PHYSICAL LANDMARKS FOR REPEATED ACCURACY CHECKS

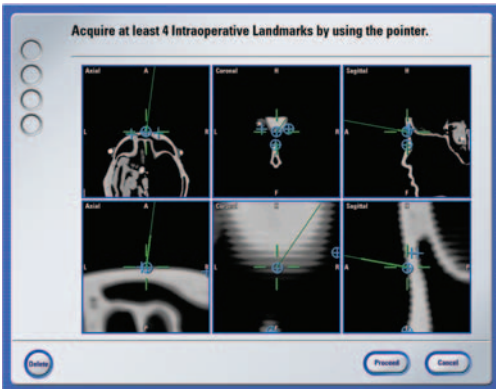
For better accuracy control throughout the procedure, it is recommended to define physical landmarks that can be used for verification during the procedure. They should be taken soon after the initial registration.



- Mark a landmark on the patient's anatomy with a pen or a drill that will not shift during the procedure, e.g., on the bone around the rim of the planned craniotomy.
- Place the instrument tip on the landmark and press **Acquire** to digitize the landmark.
- Verify the position of the acquired landmarks repeatedly during the procedure.
- Press **Display Distances** in the **Tools > Measurement** menu.
- The software displays the distance to the digitized landmarks if the current instrument position is within 8 mm distance.

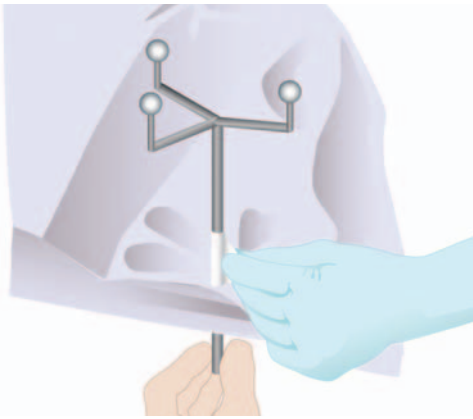
10. ACQUIRE INTRAOPERATIVE LANDMARKS TO RESTORE YOUR REGISTRATION IF NECESSARY

If you have already performed registration (standard or surface matching), you can acquire intraoperative landmarks, which can be used for re-registration at any point during surgery. This feature provides a backup mechanism if e.g., the reference array is accidentally moved or the patient is repositioned and therefore the initial registration is no longer accurate:



- Open the **Registration** menu and select **Acquire Intraoperative Landmarks**. Define as many anatomical landmarks as possible (at least 4) that will be accessible and precisely identifiable throughout the surgery, e.g., on the bone around the rim of the planned craniotomy.
- If a re-registration is required, open the **Registration** menu and select **Register Intraoperative Landmarks** for re-registration and verify the result afterwards.



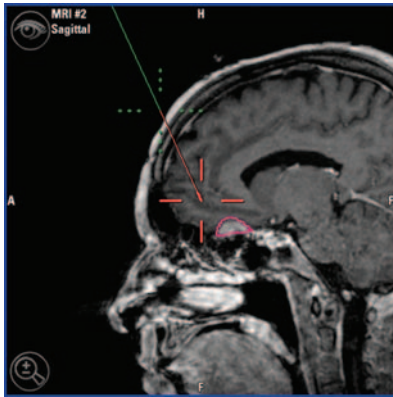


11. DETAILED VERIFICATION AFTER DRAPING

To ensure that the accuracy has not decreased during the draping procedure:

- Verify according to the description in steps 8 and 9 of this document, especially in multiple widely distributed areas, in or near to the region of interest, at recommended landmarks (e.g., tragi, inion, bregma or teeth in the upper jaw).

Verify at least one landmark on the contralateral side of the reference array (i.e., further away from the reference array than your region of interest).



12. VERIFICATION THROUGHOUT PROCEDURE

- Repeat verification after drilling or craniotomy.
- Repeat verification after completion of biopsy or resection.
- Verify the accuracy repeatedly during the procedure, whenever the accuracy check message appears.
- During the procedure, verify directly on the bone and/or on the acquired landmarks.
- Do not verify accuracy on brain tissue. The Brainlab cranial navigation system uses scanned images of the patient that are acquired before the operation is performed. The actual anatomy of the patient could differ from the preoperative image data due to e.g., brain shift or resections.



Be aware that the Brainlab cranial navigation system solely provides assistance to the surgeon and does not substitute or replace the surgeon's experience and/or responsibility during its use.

Before patient treatment, always review the plausibility of all information input to and output from the system.

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