



User's Guide

Everything you need to know about Bionavi
image guided navigation System.



Disclaimer

This manual is a reference to the use of the image guided navigation system Bionavi.



Important

For correct use

The equipment must be handled with care, this means you should avoid shocks or abrupt movements.

The user must ensure that conditions of use are appropriate, it is advisable to use the equipment in a place with safe electrical flow.

When you are not using the equipment it should be covered with its protective lining, avoid using it if it is wet and replace if it is damaged or broken.

Avoid operating the equipment in places with excess lighting, outdoors or very hot areas.

For proper maintenance

It is necessary to use specialized products for cleaning, the surface of the processing unit can be cleaned with a damp cloth.

Avoid exposing the equipment to high heat and high humidity.

Avoid forced storage, shock and exposure to abrasives.

Highest precision

The BioNavi counts with the most precise camera in the industry, its IR technology reaches a precision range of 0.12mm, duplicating the precision of the cameras of other similar systems available, it has a range of 3 meters. It allows visualization of different instruments at the same time.

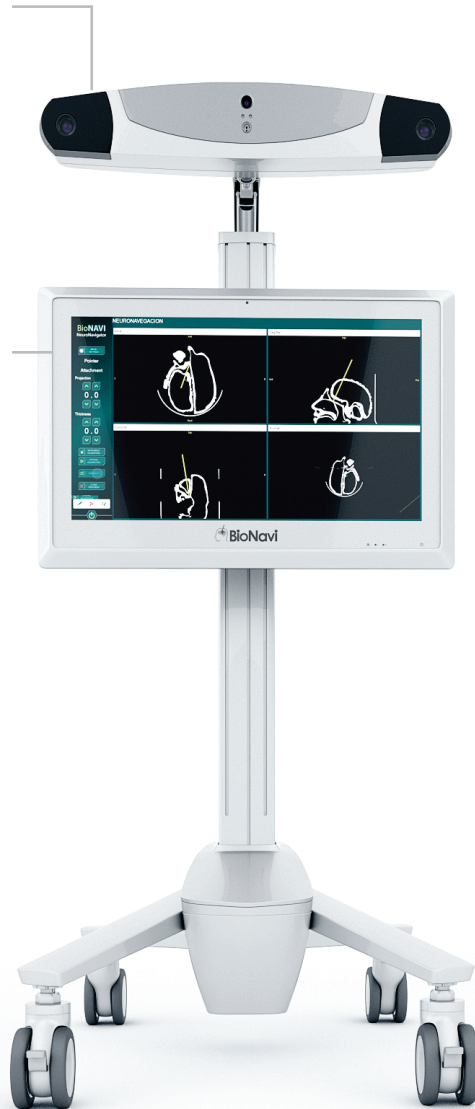
Touchscreen Monitor medical grade

Touchscreen technology, it's 22" screen shows all of the functions of the navigation system in high definition, it has a dropdown menu with multiple functions that facilitate the visualization of the system in three different dimensions.

- Antimicrobial germ protection
- Anti Glare and anti reflective technology
- Internal battery for up to 60 minutes run time



About our
technology



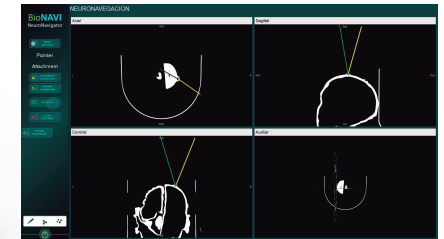
Frameless Biopsy:

The calibration system of the frameless stereotactic needle takes three seconds to calibrate a stereotactic needle with high precision, this designed mechanism simplifies the calibration process to one step, the guide arm allows to locate the desired vector quickly and through the virtual extension it can reach the desired spot to take the biopsy without the need of a frame.



Vectors Visual Extension

Through this function, you can do surgical planning before the surgery selecting the most secure approach for the patient. The pointer's virtual extension allows more precision when planning the surgery.



Instruments simultaneous view

The system allows at the same time to view different instruments to use them more thoroughly

Tablet

Wireless touchscreen monitor extension at medical grade that allows control of the navigation.



03

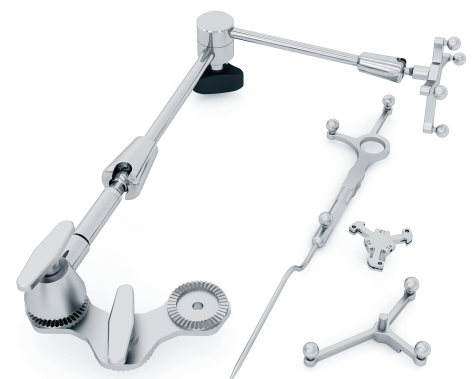
Camera

IR technology reaches a precision range of 0.12mm



Ergonomic Instruments

The system simplifies the navigation, it makes it easier and user friendly, the instruments were designed by surgeons and are absolutely ergonomic and precise at the time of surgery.



User's guide

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Disclaimer

This manual is a reference to the use of the navigation system BioNAVI.
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Bionavi System Parts



The system includes a set of items attached in a special structure.



- 1 Tracking camera
- 2 Camera lens
- 3 Adjustable arm
- 4 CPU
- 5 Power Button
- 6 CPU status LEDs
- 7 Medical cart
- 8 Brakes

Bionavi System Parts



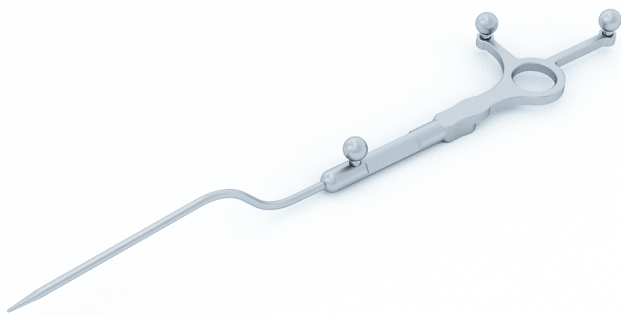
Element	Description
1 Tracking camera	Camera with IR technology.
1 Processing unit	The integrated equipment.
1 Transport unit	Is the structure that integrates the processing unit, camera and every instrument giving it mobility and protection.
1 Protective cover	Protective lining for protection against external elements.
Power cables	Power cables and voltage adapters.
1 Pointer tool	Standard pointer of the BioNavi system, it has three pivots to adjust the tracking spheres.
1 Reference tool	A four pieces star to adjust tracking spheres, it is used as reference during the process of navigation.
IR spheres	Standard tracking spheres.
Fiducial markers	Group of cylindrical pieces used as markers on the patient.



Tracking camera

The camera is a specialized device used for calculating coordinates of objects in space, its function is to track the instruments recorded in the system, usually found attached to the extension arm.

The camera requires a USB adapter, a power adapter, a USB cable and a standard powercard. (inside the equipment)



BioNavi standard pointer

Instrument built in surgical materials, is reusable and sterilizable, this is the instrument that is tracked by the camera, the view on the software is updated with the position of the tip of the instrument. It is required to use three spheres in order to use the pointer.



BioNavi standard reference star

Star-shaped instrument built in surgical materials, it can be reusable and sterilized, this instrument must be attached to the patient to form a rigid assembly, once fixed, the reference star can't be moved during the procedure. It is required to use four spheres in order to use the reference star.

The arm position can be adjusted with the screw and it can be attached to the cranial fixation (Mayfield).



Biopsy needle guide arm

Once the needle is calibrated it will help find the right vector for the stereotactic biopsy needle.

How to use it:

- 1) Calibrate the needle on the pivot point of the reference star.
- 2) Use one of the 3 different diameter of the needle guide arm to introduce the needle (1.9mm, 2.2mm or 2.6mm)
- 3) The needle can be adjusted with the screw to the guide arm.
- 4) To calculate the right vector of the needle use the attachment projection.



Multi-Modality Markers

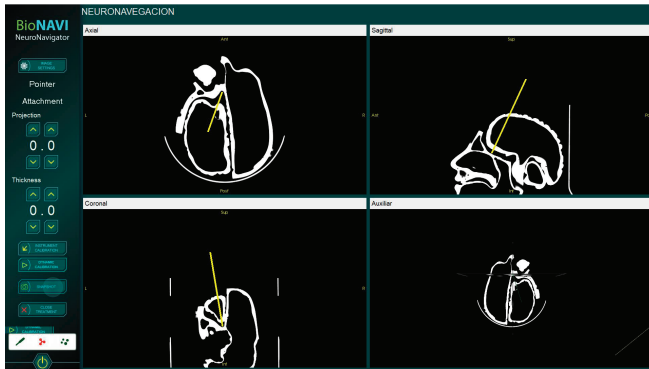
Multi-Modality Markers are artificial fiducial markers that provide a clear and accurate reference point on any type of scan. They are easy attach and remove from patients and display as a bright object on all imaging modalities.

Its function is to help conduct a proper registration and obtain accurate tracking references. They are placed over the target area of the patient (at least 5 markers in strategic positions) before the patient's image is going to be taken and before the surgery navigation, in both cases the markers must be in the same places.



IR Spheres

To place the ball in the tips of the instruments press against the sphere's opening, this will come under slight pressure and remain tight.



BioNavi software

Designed with simplicity and usefulness the BioNavi software is assembled in two areas: The action side bar and the center view.

The omniscient action sidebar at the left is where most user interaction will be done, the larger area is the main view.

This area is used for user interaction, it offers a group of contextual controls to allow the sidebar to change its controls according to the program context we will find that the controls in the sidebar at the beginning of the software are just 4 buttons: 'New treatment', 'Select treatment', 'Load treatment' and 'Shutdown' but once the treatment is loaded another set of buttons will appear.

The workflow is divided into three parts: Pre surgery preparation , right before the navigation and during the navigation.

Pre Surgery preparation

Get the pre-operative images in DICOM format.

1. Preparation of the patient: place the markers arranged according to type of operation.
2. Get the CT or MRI images in DICOM format. (Gantry in zero degrees in CT)
 - Slices 0.625 up to 1mm in CT
 - Volumetric mode in MRI
 - CT with contrast
 - MRI T1 + Contrast axial viewing

Right before the navigation:

1. Load the disk images in the program.
2. Locate the image fiducials in the image.
3. Set other options required as display settings, etc.

During the navigation.

1. Verify that the patient has the markers in the same position as when the images were taken.
2. Proceed to load the disc with the images.
3. Register the fiducial markers and accept the registration.
4. Verify the accuracy between the pointer and the image displayed by the system.

Starting a Navigation Session



The user must have a USB memory DICOM image data of the patient, with a MRI or CT scan. Equip and prepare the camera to observe well the objective.

Preparing the Camera

Before using the equipment, the user should make sure that all of the parts are connected and turned on and the camera should be positioned in a way that you can observe the patient.

Verify that the camera is connected to the processor through the USB cable and to the power source.

Prepare the equipment

Make sure to connect the equipment and camera's power cord, push the ON button located at the lower right hand side of the screen.

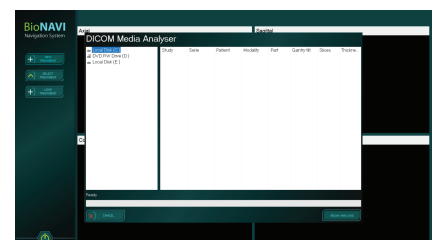
Preparing the instruments

Adjust the IR spheres on the stars and the pointer.

Downloading the patient's data

Once you connect the USB memory with the patient's data to the USB port you can click the "start" button located at the top of the screen and this will start to download the patient's data and a window will pop out showing the download progress. Once finished you will be prompted to confirm the file on a pop out window with the patient's name, if you cancel you will go back to the start, and if you confirm then you will continue to register the fiducial markers.

At the registration stage the program will ask you to activate the marker's button when the pointer is at the specified position.



Starting a Navigation Session

Registering the fiducial markers

For this step, put the pointer on the fiducial marker shown on the screen and press the "Register" button, once the marker is accepted the system will highlight the next marker on the screen and the user will have to put the pointer on the marker on the patient and confirm again, once all of the fiducial markers are processed the "Finish" button will pop out highlighted in green and the user will be able to get the accuracy of the equipment, if acceptable the navigation process will start otherwise the system will ask to register the markers again.



On the lower part of the screen there is a window with the following icons: Reference, pointer attachment these are the trace witnesses, if one of them turns gray it means that the instrument is out of the trace range of the camera, if one of them turns red it means that the camera can't find the instrument, when both are green it means that the camera can see and track the instruments.

It is very important that both windows are green at all times.

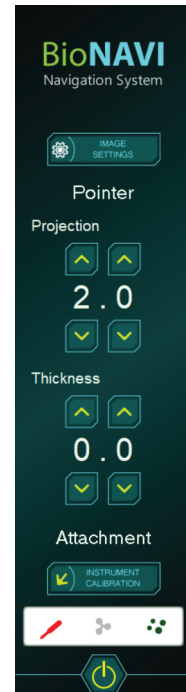
Navigation

During the navigation stage, the user can get immediate answer of the position of the pointer in relation to the patient through the pre-operation image.

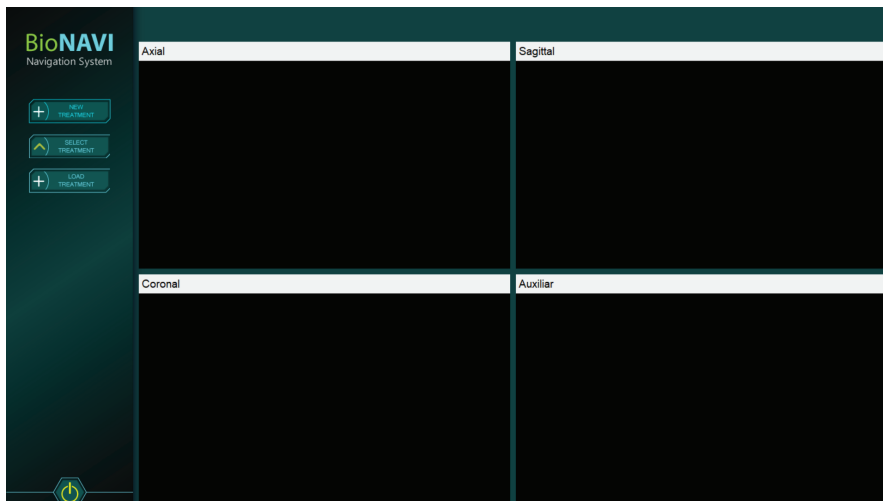
During the navigation process the user can go back to the initial stage to download another image or turn off the system, the trace witnesses work the same as they do at the fiducial marker registration stage, remember to check the status of the witnesses.



Visualization



Standard Views



Bionavi Troubleshooting



Tracking Camera

Camera does not turn: Verify the cables are properly connected and the light is on. (This indicates the adapter is active)

If you request a service, this does not respond to the dealer maintenance.

Red light appears: It is a problem of camera calibration because of a physical blow, it must be re-calibrated by qualified personnel.

Navigation

Tracking has no required precision: If you find the system is not calibrated check the camera lights and make a record with a greater number of fiducials, in case you are not satisfied with the trace request a maintenance service to the dealer.

Data disk not loaded: Verify the USB memory is in good condition and that has absolutely nothing except the data disc in it, finally check the computer reads the connected memory.