

- c. If desired, change filter, gain, and LFP settings by clicking the "Electrode Settings" button on the computer screen. Change software preferences by clicking the "Settings" button on the computer screen. Remember to update the current user profile to save changes.
- d. Check electrode impedance by clicking the "Impedance Check" button on the computer screen and pressing the orange activate button on the stimulation remote control.
- e. Record events using the "Event/Recording" (for single channel recording) and "Record All" buttons (for multi-channel recording) or by right-clicking on the channel thumbnails on the "Electrode" tab.
- f. Create voice recordings by pressing and holding the small black button on the stimulation remote control.
- g. Click the "Stimulation" button on the computer screen to enter stimulation mode. Select either "Microstim" or "Macrostim" from the pull-down menu. Control stimulation amplitude using the knob. Start/stop stimulation using the orange activate button on the stimulation remote control. If desired, stimulation may be stopped by pressing the orange activate button again (during fixed-duration mode only).

**WARNING:** Electrodes and microelectrode cables are single-use items. Do not attempt to sterilize and re-use. Dispose of electrodes according to hospital protocol.

**WARNING:** Use of non-supported electrodes can result in poor quality recordings, incorrect stimulation, inaccurate targeting, or patient injury.

**WARNING:** Electrodes and electrode cables should be connected one at a time. Be careful to assign electrode tracks and electrode contacts correctly.

**WARNING:** Route electrode lead cables carefully to avoid a tripping hazard or possible contamination of the sterile field.

**WARNING:** Never leave a microelectrode cable connected to the Guideline 4000 LP+™ if it is not connected to an electrode.

**WARNING:** Do not connect the electrode cables to earth.

**WARNING:** Auxiliary inputs are provided to monitor additional biological signals. Do not rely upon the auxiliary inputs as the sole means of tracking vital signs.

**WARNING:** The auxiliary inputs and outputs are not isolated. Do not make direct connections between the auxiliary inputs/outputs and the patient.

**WARNING:** Always adhere to the electrode manufacturer's recommendations with regard to the maximum amount of stimulation current applied.

**WARNING:** Do not attempt to use the Guideline 4000 LP+™ stimulator to create lesions.

**WARNING:** Never touch electrode cables while stimulating.

**WARNING:** Use caution when electrically stimulating a patient with existing implanted electronic devices.

**WARNING:** Monitor the patient for adverse effects during electrical stimulation.

**WARNING:** Always remove any electrodes prior to using high frequency surgical equipment. Failure to do so could result in burns at the electrode site and possible damage to the Guideline 4000 LP+™.

**WARNING:** Cables are not defibrillator proof and must be removed prior to defibrillation.

**WARNING:** To prevent the risk of shock, all electrode and electrode leads should be disconnected from the patient before defibrillation. The Guideline 4000 LP+™ is not defibrillator proof.

**WARNING:** Operation of the Guideline 4000 LP+™ in proximity of short wave or microwave therapy equipment may produce instability in the electrical stimulator output.

**WARNING:** Do not arrange electrodes and equipment in such a way that stimulation current may pass through the heart.

**CAUTION:** Incorrect setup could degrade recording and stimulation performance. Refer to equipment labeling and directions for use for instructions.

**WARNING:** Do not connect earth-referenced signals to the patient lead inputs of the Guideline 4000 LP+™.

**WARNING:** Failure to correctly set the spike discriminator thresholds may result in inaccurate or insufficient targeting information.



**CAUTION:** Keep the BNC protective covers in place when the auxiliary inputs and outputs are not in use.

**CAUTION:** Voltage read-back of stimulation output may be inaccurate when using customized waveforms and stimulation trains.

**7. Identify the implantation site.**

- a. Click on the "Raster" tab at the top of the screen to view snapshots of all recordings on all channels side-by-side.
- b. Right-click on snapshots to classify recordings. Double-click on snapshots to replay recordings.
- c. Click on the "Analysis" button to view the root-mean-square voltages of recordings plotted versus depth.
- d. Click on the "Guidance" tab at the top of the computer screen to view an illustrative model of the electrode track and surrounding structures.



**WARNING:** Do not use the illustrative model ("Guidance") as the sole indication of electrode position. This model is provided for reference only and should not be interpreted literally.

**8. Save patient data.**

- a. Patient data will be automatically preserved until the patient is deleted from the "Patient Explorer" on the left-hand side of the screen. Patient data can be exported to a file (.glr file format) by clicking the "Patient" button and selecting "Export." Multiple patients can be saved to an archive (.gla file format) by clicking the "Patient" button and selecting "Archive."

**9. Shut down the Guideline 4000 LP+™.**

- a. Shut down the LP+ by clicking the "System" button and selecting "Shutdown".
- b. Wait until the computer fully shuts down, then power off the LP+, speakers, and microTargeting™ Controller.



**WARNING:** Do not expose the Guideline 4000 LP+™ to humidity of greater than 95%.

**WARNING:** Do not store the Guideline 4000 LP+™ near or expose it to strong magnetic fields.

**WARNING:** Do not allow any liquid to contact any Guideline 4000 LP+™ component.

**CAUTION:** Only qualified FHC representatives may calibrate the Guideline 4000 LP+™.

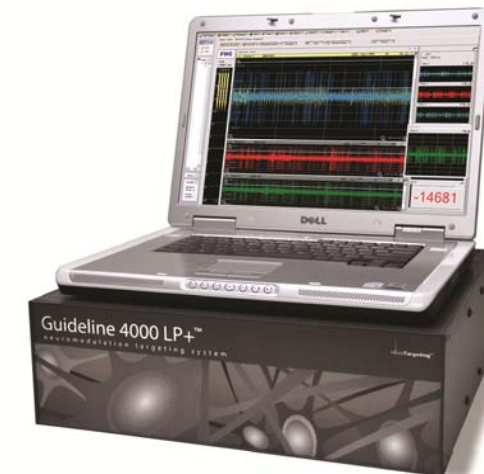
**Note:** Please reference the Directions for Use for other devices as needed:

- microTargeting™ STar™ Drive
- microTargeting™ Drive
- microTargeting™ Electrodes
- microTargeting™ Drive Accessories

"Innovation through collaboration"

# Guideline 4000 LP+™

## neuromodulation targeting system



### Directions for Use

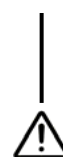
L011-57 (Rev. A1, December 2011)

**Indications for use:** The microTargeting™ Guideline 4000 LP+™ neuromodulation targeting system is intended to assist in functional neurosurgical procedures where recording from and stimulation of brain motor and sensory neurons will aid in the placement of depth electrodes.

**Intended Use:** The Guideline 4000 LP+™ neuromodulation targeting system is intended to be used by a neurosurgeon, neurologist or clinical neurophysiologist to accurately position depth electrodes during functional neurosurgical procedures.

**Applicable Standards:**

*General Standard:* EN60601-1 General Electrical Safety  
*Collateral Standards:* 60601-1-1, 60601-1-2, 60601-1-4, 60601-1-4, 60601-1-6  
*Particular Standard:* EN60601-2-26  
 The Guideline 4000 LP+™ is a Class 1 medical device with a type BF applied part.



- CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physician.
- WARNING:** The Guideline 4000 LP+™ does no analysis, diagnosis, or monitoring for undesirable or dangerous physiological conditions.
- WARNING:** The Guideline 4000 LP+™ issues no alarms should undesirable or dangerous medical conditions arise.
- WARNING:** The Guideline 4000 LP+™ must be operated by a person who has been trained by an FHC authorized representative and has read and understood the directions for use (DFU).
- WARNING:** The Guideline 4000 LP+™ must be installed by an FHC authorized representative.
- WARNING:** Do not use the Guideline 4000 LP+™ system or any part of it as a diagnostic instrument.
- WARNING:** Potentially hazardous interactions between the Guideline 4000 LP+™ and other patient connected equipment may occur. Review the documentation associated with all such equipment for relevant warnings and restrictions prior to use with the Guideline 4000 LP+™.

**Ordering Information**

**MT-LPP:** Guideline 4000 LP+™ includes one of each of the following:  
*notebook computer, desktop speakers, optical mouse, stimulation remote control, 18" USB 2.0 cable, 2 ft audio cable, test electrode, Guideline 4000 LP+ DFU*

**Required components, sold separately:**  
**MT-LPP-LC-USA** (1) Line cord (USA)  
**66-EL-LC-XXX** (1) Line cord, non-USA, specific to country of use  
**66-EL-LP** (1) microTargeting™ electrode cable for LP+

**Accessories, sold separately:**  
 MT-LPP-APM: Extra channel, up to five channels per LP+  
 MT-LPP-BOX: Breakout box for data export  
 40-42-1-01: QuickWave function generator  
 mTD type electrodes  
 ST-DS-ME: microTargeting™ STar™ Drive  
 ST-DS-MA: microTargeting™ STar™ Drive, Manual System  
 66-DS-PA: microTargeting™ Controller and Power Assist System  
 66-DS-PD: microTargeting™ Controller and Position Display Assembly  
 SERV-WAR-LPP: Guideline 4000 LP+™ one year service warranty

### System Maintenance and Repair

**Handling Considerations**

- The Guideline 4000 LP+™ is intended to be used in a standard operating room environment.
- Store the Guideline 4000 LP+™ at room temperatures between 0°C (32°F) and 40°C (104°F).
- Neither the Guideline 4000 LP+™ nor its components are designed for sterilization.
- Do not drop the Guideline 4000 LP+™ or its components.
- Only transport the Guideline 4000 LP+™ inside of its shipping container, with included foam insulation.

**End-of-Life System Disposal**

- Return the Guideline 4000 LP+™ to FHC for proper end-of-life disposal. Please contact an FHC factory authorized representative to arrange a return.

**Maintenance**

- The Guideline 4000 LP+™ must be inspected and recalibrated each year by an FHC authorized representative. Contact FHC for more information on Service Agreements and Preventive Maintenance Programs.
- The Guideline 4000 LP+™ and its components may be cleaned by wiping a dry rag lightly over all surfaces. If necessary, a slightly damp cloth moistened with a standard hospital disinfectant may be used.

**Repair**

- All FHC products are unconditionally guaranteed against defects in workmanship for one year from the date of shipment, provided they have been exposed to normal and proper use.
- Should service or repair be required, please contact FHC at 1-800-326-2905 (US & Canada) or +1-207-666-8190 for return instructions.

**Password Reminder:**

